KYNMOBI- apomorphine hydrochloride film, soluble
KYNMOBI- apomorphine hydrochloride
Sunovion Pharmaceuticals Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use KYNMOBI safely and effectively. See full prescribing information for KYNMOBI.

KYNMOBI™ (apomorphine hydrochloride) sublingual film
Initial U.S. Approval: 2004

INDICATIONS AND USAGE

KYNMOBI is a non-ergoline dopamine agonist indicated for the acute, intermittent treatment of "off" episodes in patients with Parkinson's disease (1)

DOSAGE AND ADMINISTRATION

- For sublingual administration only (2.1)
- Dose initiation should be supervised by a healthcare provider (2.1, 2.3)
- Treatment with a concomitant antiemetic, e.g. trimethobenzamide, is recommended, beginning 3 days prior to initial dose of KYNMOBI (2.1, 5.1)
- The dose range for KYNMOBI is 10 mg to 30 mg per dose, administered sublingually, as needed (2.2)
- KYNMOBI doses should be separated by at least 2 hours (2.2)
- Maximum of 5 doses per day; maximum single dose is 30 mg (2.2, 2.3)

DOSAGE FORMS AND STRENGTHS

KYNMOBI sublingual film: 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg of apomorphine hydrochloride (3, 16)

CONTRAINDICATIONS

- Concomitant use of KYNMOBI with 5HT3 antagonists (4)
- Hypersensitivity to apomorphine or any of its ingredients including sodium metabisulfite (4)

WARNINGS AND PRECAUTIONS

- Nausea and vomiting may occur (2.1, 5.1)
- Falling asleep during activities of daily living and daytime somnolence may occur, discontinue KYNMOBI if occurs (5.2)
- Syncope and hypotension/orthostatic hypotension may occur, monitor blood pressure (5.3)
- Oral mucosal irritation may occur, which may require pausing or discontinuing treatment (5.4)
- Falls may occur, or increase (5.6)
- May cause hallucinations and psychotic-like behavior (5.7)
- May cause impulse control and impulsive behaviors; consider dose reduction or discontinuing KYNMOBI if occurs (5.8)
- Withdrawal-emergent hyperpyrexia and confusion may occur with rapid dose reduction or withdrawal (5.9)
- May prolong QTc and cause torsades de pointes or sudden death; consider risk factors prior to initiation (5.10)

ADVERSE REACTIONS

Most common adverse reactions (incidence at least 10% in patients treated with KYNMOBI and with an incidence greater than placebo) were nausea, oral/pharyngeal soft tissue swelling, oral/pharyngeal soft tissue pain and paraesthesia, dizziness, and somnolence (6.1)
To report SUSPECTED ADVERSE REACTIONS, contact Sunovion Pharmaceuticals Inc. at 1-877-737-7226 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

DRUG INTERACTIONS

- Concomitant use of antihypertensive medications and vasodilators may increase risk for hypotension, myocardial infarction, falls and injuries (7.2)
- Dopamine antagonists may diminish the effectiveness of KYNMOBI (7.4)

USE IN SPECIFIC POPULATIONS

- Pregnancy: Based on animal data, may cause fetal harm (8.1)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 5/2020

FULL PRESCRIBING INFORMATION: CONTENTS*

17 PATIENT COUNSELING INFORMATION

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

KYNMOBI is indicated for the acute, intermittent treatment of “off” episodes in patients with Parkinson's disease (PD).

2 DOSAGE AND ADMINISTRATION

2.1 Important Administration Instructions

Dose initiation should be supervised by a healthcare provider *[see Dosage and Administration (2.3)]*.

KYNMOBI must be administered whole. Do not to cut, chew, or swallow KYNMOBI. KYNMOBI will disintegrate in about 3 minutes.

Because of the high incidence of nausea and vomiting with KYNMOBI when administered at recommended doses, an antiemetic (e.g., trimethobenzamide 300 mg three times a day), beginning 3 days prior to the initial dose of KYNMOBI, is recommended. Treatment with the antiemetic should only be continued as long as necessary to control nausea and vomiting, and generally no longer than two months after initiation of treatment with KYNMOBI *[see Contraindications (4) and Warnings and Precautions (5.1)]*.

Based on reports of profound hypotension and loss of consciousness when apomorphine was administered with ondansetron, the concomitant use of apomorphine with drugs of the 5HT3 antagonist class including antiemetics (for example, ondansetron, granisetron, dolasetron, palonosetron) and alosetron are contraindicated *[see Contraindications (4)]*.

2.2 Dosing Information

The dose range for KYNMOBI is 10 mg to 30 mg per dose, administered sublingually, as needed, for the acute, intermittent treatment of “off” episodes.

Doses should be separated by at least 2 hours. If a single dose of KYNMOBI is ineffective for a particular “off” episode, a second dose should not be given for that “off” episode. The efficacy or safety of administering a second dose for a single “off” episode has not been studied.

Do not administer more than 5 doses per day.

The maximum single dose of KYNMOBI is 30 mg.

2.3 Dose Titration

The initial dose is 10 mg. Dose initiation should occur when the patient is in an “off” state and in a setting where a healthcare provider can monitor blood pressure and pulse. In clinical studies of KYNMOBI, the “off” state was achieved by instructing patients to not take their regular morning dose of carbidopa/levodopa or any other adjunctive Parkinson's disease medications, and to take their last dose of carbidopa/levodopa and any other adjunctive Parkinson's disease medications no later than midnight the night before *[see Clinical Studies (14)]*.

If the patient tolerates the 10 mg dose, and responds adequately, the starting dose should be 10 mg, used on an as needed basis, up to 5 times per day, to treat “off” episodes. If the dose is tolerated but the

response is insufficient, the patient's usual Parkinson's disease medications should be resumed and up-titration with KYNMOBI continued generally within 3 days. Increase dosage by increments of 5 mg and assess response. Continue to titrate in a similar manner, under the supervision of a healthcare provider, until an effective and tolerable dose is achieved *[see Dosage and Administration (2.2) and Clinical Studies (14)]*.

3 DOSAGE FORMS AND STRENGTHS

KYNMOBI sublingual film is a blue to green rectangular film with a white printed number identifying the strength (e.g., "10" is 10 mg). KYNMOBI comes in dosage strengths of 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg. Each sublingual film is individually packaged in a sealed foil pouch.

4 CONTRAINDICATIONS

KYNMOBI is contraindicated in patients:

- Using concomitant 5HT3 antagonists, including antiemetics (e.g., ondansetron, granisetron, dolasetron, palonosetron) and alosetron *[see Drug Interactions (7.1)]*. There have been reports of profound hypotension and loss of consciousness when subcutaneous apomorphine was administered with a 5HT3 antagonist.
- With hypersensitivity/allergic reaction to apomorphine or to any of the ingredients of KYNMOBI. Angioedema or anaphylaxis may occur *[see Warnings and Precautions (5.3)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Nausea and Vomiting

KYNMOBI may cause nausea and vomiting when administered at recommended doses. Because of the high incidence of nausea and vomiting with KYNMOBI when administered at recommended doses, an antiemetic, e.g., trimethobenzamide 300 mg three times a day, is recommended beginning 3 days prior to the initial dose of KYNMOBI. Treatment with the antiemetic should only be continued as long as necessary to control nausea and vomiting, and generally no longer than two months after initiation of treatment with KYNMOBI *[see Dosage and Administration (2.1)]*.

In Study 1 *[see Clinical Studies (14)]*, treatment with an antiemetic (i.e., trimethobenzamide hydrochloride; 300 mg by mouth three times daily) was required beginning 3 days before starting KYNMOBI; however, it could be discontinued during the maintenance phase. During the titration phase of Study 1, nausea was reported as an adverse reaction by 21% of patients treated with KYNMOBI, while vomiting was reported as an adverse reaction by 4% of patients treated with KYNMOBI. During the maintenance phase of Study 1, nausea was reported as an adverse reaction by 28% of patients treated with KYNMOBI, compared with 4 % of patients who received placebo. During the maintenance phase of Study 1, vomiting was reported as an adverse reaction by 7% of patients treated with KYNMOBI, compared with 0 % of patients who received placebo. Nausea or vomiting was the reason for withdrawal from the study in 2% of patients treated with KYNMOBI during the titration phase and 2% of patients treated with KYNMOBI during the maintenance phase.

Concomitantly administered antiemetic drugs other than trimethobenzamide have not been studied. 5HT3 antagonist antiemetics are contraindicated *[see Contraindications (4)]*. Antiemetics with anti-dopaminergic actions (e.g., haloperidol, chlorpromazine, promethazine, prochlorperazine, metoclopramide) have the potential to worsen symptoms in patients with Parkinson's disease and should be avoided *[see Drug Interactions (7.4)]*.

5.2 Falling Asleep During Activities of Daily Living and Somnolence

Patients treated with dopaminergic medications, including apomorphine, have reported falling asleep while engaged in activities of daily living, including the operation of motor vehicles, which sometimes

has resulted in accidents. Patients may not perceive warning signs, such as excessive drowsiness, or they may report feeling alert immediately prior to the event.

During the titration phase of Study 1, somnolence was reported as an adverse reaction in 11% of patients treated with KYNMOBI. During the maintenance phase of Study 1, somnolence was reported as an adverse reaction in 13% of patients treated with KYNMOBI, compared with 2% of patients who received placebo.

Prescribers should reassess patients for drowsiness or sleepiness, especially since some of the events occur well after the start of treatment. Prescribers should also be aware that patients may not acknowledge drowsiness or sleepiness until directly questioned about drowsiness or sleepiness during specific activities.

Before initiating treatment with KYNMOBI, advise patients of the risk of drowsiness and ask them about factors that could increase the risk with KYNMOBI, such as concomitant sedating medications and the presence of sleep disorders. If a patient develops significant daytime sleepiness or falls asleep during activities that require active participation (e.g., conversations, eating, etc.), KYNMOBI should ordinarily be discontinued. If a decision is made to continue KYNMOBI, patients should be advised not to drive and to avoid other potentially dangerous activities. There is insufficient information to determine whether dose reduction will eliminate episodes of falling asleep while engaged in activities of daily living.

5.3 Hypersensitivity

Oral soft tissue swelling (lips, tongue, gingiva, and mouth) was reported as adverse reaction in 15% of patients treated with KYNMOBI during the maintenance phase of Study 1, compared with 0% of patients who received placebo; 11% of patients discontinued KYNMOBI because of this event.

Swelling of the face, oral allergy syndrome, hypersensitivity, or urticaria were reported as an adverse reaction in 6% of patients treated with KYNMOBI during the maintenance phase of Study 1, compared with 0% of patients who received placebo; 4% of patients discontinued KYNMOBI because of this event.

It is not known whether these events are related to apomorphine, sodium metabisulfite, or another KYNMOBI excipient.

KYNMOBI rechallenge is not generally recommended after discontinuation as oral adverse reactions may recur and may be more severe than the initial reaction.

Sulfite Sensitivity

KYNMOBI contains sodium metabisulfite, a sulfite that may cause allergic-type reactions, including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.

5.4 Syncope / Hypotension / Orthostatic Hypotension

KYNMOBI may cause syncope, hypotension, or orthostatic hypotension. During the titration phase of Study 1, syncope, pre-syncope, hypotension, or orthostatic hypotension were reported as adverse reactions in 4% of patients. During the maintenance phase of Study 1, syncope, pre-syncope, hypotension, or orthostatic hypotension were reported as adverse reactions in 2% of patients treated with KYNMOBI, compared with 0% of patients who received placebo.

During the maintenance phase of Study 1, systolic orthostatic hypotension (reduction of 20 mmHg or more in standing minus supine/sitting systolic blood pressure) or diastolic hypotension (10 mmHg or more for standing minus supine/sitting diastolic blood pressure) occurred in 43% of patients treated with KYNMOBI, and in 36% of patients who received placebo.

Patients treated with KYNMOBI should receive an assessment for hypotension / orthostatic

hypotension, especially if they have a history of hypotension or cardiovascular disease, or if they are currently using antihypertensive medication. Inform patients of the risk of orthostatic hypotension.

The hypotensive effects of KYNMOBI may be increased by the concomitant use of alcohol, antihypertensive medications, and vasodilators (especially nitrates). Patients should avoid alcohol when using KYNMOBI *[see Drug Interactions (7.3), Clinical Pharmacology (12.3)]*. Patients taking KYNMOBI should lie down before and after taking sublingual nitroglycerin *[see Drug Interactions (7.2), Clinical Pharmacology (12.3)]*.

Monitor patients taking concomitant antihypertensive medications for hypotension and orthostatic hypotension *[see Drug Interactions (7.2, 7.3)]*.

5.5 Oral Mucosal Irritation

During the titration phase of Study 1, oral mucosal ulceration or stomatitis were reported as adverse reactions in 2% of patients treated with KYNMOBI. During the maintenance phase of Study 1, oral mucosal ulceration or stomatitis were reported as adverse reactions in 7% of patients treated with KYNMOBI, compared with 0% of patients who received placebo *[see Adverse Reactions (6.1)]*.

During the titration of Study 1, oral soft tissue pain or paresthesia were reported as adverse reactions in 2% of patients treated with KYNMOBI. During the maintenance phase of Study 1, oral soft tissue pain or paresthesia were reported as adverse reactions in 13% of patients treated with KYNMOBI, compared with 2% of patients who received placebo.

In general, oral mucosal irritation reactions were mild to moderate severity, and usually resolved with treatment discontinuation.

KYNMOBI rechallenge is not generally recommended after discontinuation as oral adverse reactions may recur and be more severe than the initial reaction.

Hypersensitivity adverse reactions may also occur during treatment with KYNMOBI *[see Warnings and Precautions (5.3)]*.

5.6 Falls

Patients with Parkinson's disease are at risk of falling because of underlying postural instability, possible autonomic instability, and syncope caused by the blood pressure lowering effects of the drugs used to treat Parkinson's disease *[see Clinical Pharmacology (12.2)]*. KYNMOBI might increase the risk of falling by simultaneously lowering blood pressure and altering mobility *[see Warnings and Precautions (5.4)]*.

During the titration period of Study 1, falls were reported as adverse reaction in 4% of patients treated with KYNMOBI. During the maintenance period of Study 1, falls were reported as adverse reaction in 6% of patients treated with KYNMOBI, compared with 2% of patients who received placebo.

5.7 Hallucinations / Psychotic-Like Behavior

During the maintenance phase of Study 1, hallucinations, delusions, disorientation, or confusion were reported as adverse reactions in 6% of patients treated with KYNMOBI, compared with 2% of patients who received placebo. No patient developed hallucinations or psychotic-like behavior during the titration phase.

A total of 4% of patients treated with KYNMOBI discontinued treatment because of disorientation, confusional state, or delusions, compared with 2% of patients who received placebo.

Postmarketing reports with subcutaneous apomorphine indicate that patients may experience new or worsening mental status and behavioral changes, which may be severe, including psychotic-like behavior after starting or increasing the dose of apomorphine. Other drugs prescribed to improve the symptoms of Parkinson's disease can have similar effects on thinking and behavior. This abnormal thinking and behavior can consist of one or more of a variety of manifestations, including paranoid

ideation, delusions, hallucinations, confusion, disorientation, aggressive behavior, agitation, and delirium.

Patients with a major psychotic disorder should ordinarily not be treated with apomorphine because of the risk of exacerbating psychosis. In addition, certain medications used to treat psychosis may exacerbate the symptoms of Parkinson's disease and may decrease the effectiveness of KYNMOBI *[see Drug Interactions (7.4)]*.

5.8 Impulse Control/Compulsive Behaviors

Case reports suggest that patients can experience intense urges to gamble, increased sexual urges, intense urges to spend money uncontrollably, and other intense urges and the inability to control these urges while taking one or more medications, including KYNMOBI, that increase central dopaminergic tone. In some cases, although not all, these urges were reported to have stopped when the dose was reduced, or the medication was discontinued. Because patients may not recognize these behaviors as abnormal, it is important for prescribers to specifically ask patients or their caregivers about the development of new or increased gambling urges, sexual urges, uncontrolled spending, binge eating or other urges while being treated with KYNMOBI. Physicians should consider dose reduction or stopping the medication if a patient develops such urges while taking KYNMOBI.

5.9 Withdrawal-Emergent Hyperpyrexia and Confusion

A symptom complex resembling the neuroleptic malignant syndrome (characterized by elevated temperature, muscular rigidity, altered consciousness, elevated serum creatine kinase, and autonomic instability), with no other obvious etiology, has been reported in association with rapid dose reduction, withdrawal of, or changes in antiparkinsonian therapy.

5.10 QTc Prolongation and Potential for Proarrhythmic Effects

At exposures achieved with therapeutic doses of subcutaneous apomorphine, a dose-related prolongation of QTc has been observed *[see Clinical Pharmacology (12.2)]*. Although the extent of the exposure and the C_{max} of apomorphine are lower following the maximum recommended dose of KYNMOBI (30 mg) than following the maximum recommended dose of subcutaneous apomorphine (6 mg), QTc prolongation with KYNMOBI cannot be excluded.

Drugs that prolong the QTc interval have been associated with torsades de pointes and sudden death. The relationship of QTc prolongation to torsades de pointes is clearest for larger increases (20 msec and greater), but it is possible that smaller QTc prolongations may also increase risk, or increase it in susceptible individuals, such as those with hypokalemia, hypomagnesemia, bradycardia, concomitant use of other drugs that prolong the QTc interval, or genetic predisposition (e.g., congenital prolongation of the QT interval). Although torsades de pointes has not been observed in association with the use of KYNMOBI at recommended doses in clinical studies, experience is too limited to rule out an increased risk. Palpitations and syncope may signal the occurrence of an episode of torsades de pointes.

The risks and benefits of KYNMOBI treatment should be considered prior to initiating treatment with KYNMOBI in patients with risk factors for prolonged QTc.

5.11 Fibrotic Complications

Cases of retroperitoneal fibrosis, pulmonary infiltrates, pleural effusion, pleural thickening, and cardiac valvulopathy have been reported in some patients treated with ergot-derived dopaminergic agents. While these complications may resolve when the drug is discontinued, complete resolution does not always occur. Although these adverse reactions are believed to be related to the ergoline structure of these dopamine agonists, whether other, nonergot derived dopamine agonists, such as KYNMOBI, can cause these reactions is unknown.

5.12 Priapism

Apomorphine may cause prolonged painful erections in some patients. Severe priapism may require surgical intervention.

5.13 Retinal Pathology in Albino Rats

In a 2-year carcinogenicity study of apomorphine in albino rat, retinal atrophy was detected at all subcutaneous doses tested (up to 0.8 mg/kg/day or 2 mg/kg/day in males or females, respectively). Retinal atrophy/degeneration has been observed in albino rats treated with other dopamine agonists for prolonged periods (generally during 2-year carcinogenicity studies). Retinal findings were not observed in a 39-week subcutaneous toxicity study of apomorphine in monkey at doses up to 1.5 mg/kg/day. The clinical significance of the finding in rat has not been established but cannot be disregarded because disruption of a mechanism that is universally present in vertebrates (e.g., disk shedding) may be involved.

6 ADVERSE REACTIONS

The following serious adverse reactions are discussed in more detail in the Warnings and Precautions section of labeling:

- Nausea and Vomiting *[see Warnings and Precautions (5.1)]*
- Falling Asleep During Activities of Daily Living and Somnolence *[see Warnings and Precautions (5.2)]*
- Hypersensitivity *[see Warnings and Precautions (5.3)]*
- Syncope/Hypotension/Orthostatic Hypotension *[see Warnings and Precautions (5.4)]*
- Oral Mucosal Irritation *[see Warnings and Precautions (5.5)]*
- Falls *[see Warnings and Precautions (5.6)]*
- Hallucinations/Psychotic Behavior *[see Warnings and Precautions (5.7)]*
- Impulse Control/Compulsive Behaviors *[see Warnings and Precautions (5.8)]*
- Withdrawal-Emergent Hyperpyrexia and Confusion *[see Warnings and Precautions (5.9)]*
- *QTc Prolongation and Potential for Proarrhythmic Effects [see Warnings and Precautions (5.10)]*
- Fibrotic Complications *[see Warnings and Precautions (5.11)]*
- Priapism *[see Warnings and Precautions (5.12)]*
- Retinal Pathology in Albino Rats *[see Warnings and Precautions (5.13)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to the rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

KYNMOBI safety data presented below is derived from a randomized, double blind, placebo-controlled study in patients with Parkinson's disease (Study 1) *[see Clinical Studies (14)]*. Study 1 included a titration phase, in which 141 patients received at least one dose of KYNMOBI, followed by a placebo-controlled 12-week maintenance phase. The mean age of patients in Study 1 was 63 years (range 43 to 86 years); 63% of patients were male, and 93% were Caucasian.

The most common adverse reactions (incidence at least 10% in patients treated with KYNMOBI and with an incidence greater than placebo) were nausea, oral/pharyngeal soft tissue swelling, oral/pharyngeal soft tissue pain and paraesthesia, dizziness, and somnolence.

Adverse reactions led to discontinuation of KYNMOBI in 9% of patients in the titration phase, and 28% of patients in the maintenance phase, compared with 7% of patients on placebo (in the maintenance phase). The most common adverse reactions leading to discontinuation during the maintenance phase were oral/pharyngeal soft tissue swelling, oral mucosal erythema, and nausea/vomiting.

Table 1 presents the adverse reactions that occurred in at least 5% of patients treated with KYNMOBI during the maintenance phase of Study 1, and with an incidence greater than in patients who received

placebo.

Table 1: Adverse Reactions Reported by at Least 5% of Patients Treated with KYNMOBI during the Maintenance Phase of Study 1, and with an Incidence Greater than Placebo

	Titration	Maintenance	
	KYNMOBI (N=141) %	KYNMOBI (N=54) %	Placebo (N=55) %
Gastrointestinal disorders			
Nausea	21	28	4
Oral/pharyngeal soft tissue swelling[1]	1	15	0
Oral/pharyngeal soft tissue pain and paraesthesia[2]	2	13	2
Oral ulceration and stomatitis[3]	2	7	0
Oral mucosal erythema	4	7	4
Vomiting	4	7	0
Dry mouth	1	6	0
Nervous system disorders			
Somnolence	11	13	2
Dizziness	11	9	0
Headache	8	6	0
Respiratory, thoracic, and mediastinal disorders			
Rhinorrhea	6	7	0
General disorders and administration site conditions			
Fatigue	3	7	0
Injury, poisoning, and procedural complications			
Fall	4	6	2
Laceration	1	6	0
Skin and subcutaneous tissue disorders			
Hyperhidrosis	4	6	4
Immune system disorders			
Hypersensitivity[4]	0	6	0

[1] Includes lip swelling, lip edema, oropharyngeal swelling, gingival edema, edema mouth, swollen tongue, and pharyngeal edema

[2] Includes throat irritation, glossodynia, oral pain, oral paresthesia, oropharyngeal pain, gingival pain, and oral hypoesthesia

[3] Includes lip ulceration, oral mucosal blistering, stomatitis, cheilitis, and tongue ulceration

[4] Includes hypersensitivity, swelling face, oral allergy syndrome and urticaria

Less Common Adverse Reactions

Other adverse reactions including hallucinations, delusions, and impulse control disorder have been reported in patients treated with KYNMOBI *[see Warnings and Precautions (5.7, 5.8)]*.

Vital Sign Changes

Blood Pressure

Decreases in blood pressure have been observed in patients treated with KYNMOBI. During the titration phase of Study 1, syncope, pre-syncope, hypotension, or orthostatic hypotension were reported as adverse reaction in 4% of patients treated with KYNMOBI. During the maintenance phase of Study 1, syncope, pre-syncope, hypotension, or orthostatic hypotension were reported as adverse reaction in 2

% of patients treated with KYNMOBI, compared with 0% of patients who received placebo *[see Warnings and Precautions (5.4) and Clinical Pharmacology (12.2)]*.

7 DRUG INTERACTIONS

7.1 5HT3 Antagonists

Based on reports of profound hypotension and loss of consciousness when subcutaneous apomorphine was administered with ondansetron, the concomitant use of KYNMOBI with 5HT3 antagonists, including antiemetics (e.g., ondansetron, granisetron, palonosetron) and alosetron, is contraindicated *[see Warnings and Precautions (5.4)]*.

7.2 Antihypertensive Medications and Vasodilators

In a study of healthy subjects, concomitant administration of 0.4 mg sublingual nitroglycerin with subcutaneous apomorphine caused greater decreases in blood pressure than with subcutaneous apomorphine alone *[see Clinical Pharmacology (12.3)]*.

Patients taking KYNMOBI should lie down before and after taking sublingual nitroglycerin *[see Warnings and Precautions (5.4)]*.

7.3 Alcohol

In a study of healthy subjects, concomitant administration of high dose (0.6 g/kg) or low dose (0.3 g/kg) ethanol with subcutaneous apomorphine caused greater decreases in blood pressure than with subcutaneous apomorphine alone *[see Clinical Pharmacology (12.3)]*.

Patients should avoid drinking alcohol after using KYNMOBI *[see Warnings and Precautions (5.4)]*.

7.4 Dopamine Antagonists

Since KYNMOBI is a dopamine agonist, it is possible that concomitant use of dopamine antagonists, such as the neuroleptics (e.g., phenothiazines, butyrophenones, thioxanthenes) or metoclopramide, may diminish the effectiveness of KYNMOBI. Antiemetics with anti-dopaminergic actions should be avoided *[see Warnings and Precautions (5.1)]*. Patients with major psychotic disorders receiving neuroleptics should be treated with dopamine agonists only if the potential benefits outweigh the risks *[see Warnings and Precautions (5.7)]*.

7.5 Drugs Prolonging the QT/QTc Interval

Caution should be exercised when prescribing KYNMOBI concomitantly with drugs that prolong the QT/QTc interval *[see Warnings and Precautions (5.10) and Clinical Pharmacology (12.2)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate data on the developmental risk associated with use of KYNMOBI in pregnant women. In animal reproduction studies, apomorphine had adverse developmental effects in rats (increased neonatal deaths) and rabbits (increased incidence of malformation) when administered during pregnancy at clinically relevant doses. These doses were also associated with maternal toxicity *[see Data]*. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. The background risk of major birth defects and miscarriage for the indicated population is unknown.

Data

Animal Data

No adverse developmental effects were observed when apomorphine (0.3, 1, or 3 mg/kg/day) was administered by subcutaneous injection to pregnant rats throughout organogenesis. Administration of apomorphine (0.3, 1, or 3 mg/kg/day) by subcutaneous injection to pregnant rabbits throughout organogenesis resulted in an increased incidence of malformations of the heart and/or great vessels at the mid and high doses; maternal toxicity was observed at the highest dose tested.

Apomorphine (0.3, 1, or 3 mg/kg/day), administered by subcutaneous injection to females throughout gestation and lactation, resulted in increased offspring mortality at the highest dose tested, which was associated with maternal toxicity. There were no effects on developmental parameters or reproductive performance in surviving offspring.

8.2 Lactation

Risk Summary

There are no data on the presence of apomorphine in human milk, the effects of apomorphine on the breastfed infant, or the effects of apomorphine on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for KYNMOBI and any potential adverse effects on the breastfed infant from KYNMOBI or from the underlying maternal condition.

8.4 Pediatric Use

The safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

Clinical studies of KYNMOBI did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. In Study 1, 78 patients below 65 years of age and 63 patients 65 years of age or older received at least one dose of KYNMOBI. Clinical experience with subcutaneous use of apomorphine has shown that the following adverse reactions were reported more frequently in patients 65 years of age or older compared to patients less than 65 years of age: confusion; hallucinations; serious adverse reactions (life-threatening events or events resulting in hospitalization and/or increased disability); fall (experiencing bone and joint injuries); cardiovascular events; respiratory disorders; gastrointestinal events; and discontinuation of treatment as a result of one or more adverse reactions.

In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

8.6 Renal Impairment

Avoid use of KYNMOBI in patients with severe and end-stage renal disease (ESRD) (CLcr <30 mL/min). No dosage adjustment is required for patients with mild or moderate renal impairment. However, because of a potential for increased exposure, titrate KYNMOBI under medical supervision *[see Dosage and Administration (2.3) and Clinical Pharmacology (12.3)]*.

8.7 Hepatic Impairment

Avoid use of KYNMOBI in patients with severe hepatic impairment (Child-Pugh Class C). No dosage adjustment is required for patients with mild or moderate hepatic impairment (Child-Pugh Class A and B). However, because of a potential for increased exposure, titrate KYNMOBI under medical supervision *[see Dosage and Administration (2.3) and Clinical Pharmacology (12.3)]*.

9 DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance

KYNMOBI contains apomorphine, which is not a controlled substance.

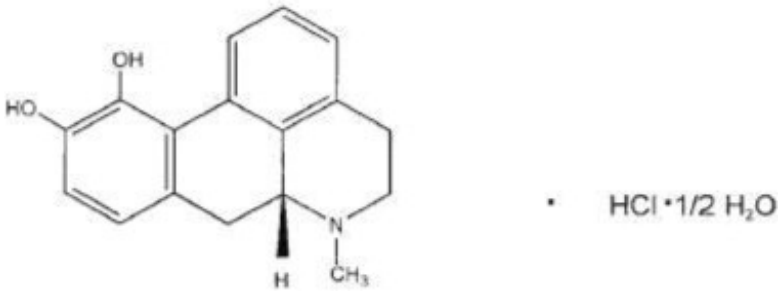
9.2 Abuse

In premarketing clinical experience, KYNMOBI did not reveal any tendency for a withdrawal syndrome or any drug-seeking behavior. However, there are rare postmarketing reports of abuse of medications containing apomorphine. Abuse is the intentional, non-therapeutic use of a drug, even once, for its desirable psychological or physiological effects. In general, these reports for apomorphine consist of patients taking increasing doses of medication in order to achieve a euphoric state.

11 DESCRIPTION

KYNMOBI (apomorphine hydrochloride) sublingual film contains apomorphine hydrochloride, a non-ergoline dopamine agonist. Apomorphine hydrochloride is chemically designated as 6aβ-Aporphine-10,11-diol hydrochloride hemihydrate with a molecular formula of $C_{17}H_{17}NO_2 \cdot HCl \cdot ½\ H_2O$. Its structural formula and molecular weight are:

Figure 1: Structural Formula and Molecular Weight of Apomorphine Hydrochloride



The molecular weight is 312.79 (hydrochloride hemihydrate salt).

Apomorphine hydrochloride is white to grayish glistening crystals or white powder that is sparingly soluble in water and alcohol at ambient temperature.

KYNMOBI is intended for sublingual administration only and is available in five dosage strengths. Each film contains 10 mg, 15 mg, 20 mg, 25 mg, or 30 mg of apomorphine hydrochloride (equivalent to 8.8 mg, 13.2 mg, 17.6 mg, 22.0 mg, and 26.4 mg of apomorphine, respectively). Each film also contains the following inactive ingredients: disodium EDTA, dihydrate, FD&C Blue #1, glycerol, glyceryl monostearate, hydroxyethyl cellulose, hypromellose, maltodextrin, (-)-menthol, pyridoxine hydrochloride, sodium hydroxide, sodium metabisulfite, sucralose, and white ink.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

KYNMOBI is a non-ergoline dopamine agonist with high in vitro binding affinity for the dopamine D_4 receptor, and moderate affinity for the dopamine D_2, D_3, and D_5, and adrenergic α_1D, α_2B, α_2C receptors. The precise mechanism of action of KYNMOBI as a treatment for “off” episodes associated with Parkinson's disease is unknown, although it is believed to be due to stimulation of post-synaptic dopamine D_2-type receptors within the caudate-putamen in the brain.

12.2 Pharmacodynamics

Cardiac Electrophysiology

In a thorough QT study with subcutaneous apomorphine at exposures similar to those achieved with the recommended subcutaneous apomorphine dosing (i.e, 6 mg), apomorphine resulted in a prolongation of QTcF of 10 msec (90% upper confidence interval of 16 msec). The thorough QT study also identified a significant exposure-response relationship between apomorphine concentration and QTcF.

Although the extent of the exposure and the C_{max} of apomorphine are lower following the maximum recommended dose of KYNMOBI (30 mg) than following the maximum recommend dose of subcutaneous apomorphine (6 mg), QTc prolongation with KYNMOBI cannot be excluded.

Decreases in Blood Pressure

In Study 1, systolic orthostatic hypotension (reduction of 20 mmHg or more in standing minus supine/sitting systolic blood pressure) or diastolic hypotension (10 mmHg or more for standing minus supine/sitting diastolic blood pressure) occurred in 43% of patients treated with KYNMOBI, compared to 36% of patients who received placebo *[see Warnings and Precautions (5.4) and Drug Interactions (7.2, 7.3)]*.

12.3 Pharmacokinetics

Absorption

Following sublingual administration of 15 mg of apomorphine, the time to maximum concentration (Tmax) ranged from 0.5 to 1 hour. Apomorphine exhibits less than dose proportional increase in exposures over a dose range of 10 mg to 35 mg (1.2 times the highest recommended dosage) following a single sublingual administration of KYNMOBI in patients with Parkinson's disease.

Distribution

Following sublingual administration of 15 mg of apomorphine, the geometric mean (CV%) of the apparent volume of distribution was 3630 L (66%).

Elimination

Metabolism

The major metabolic pathways for sublingual apomorphine are sulfation by multiple sulfotransferase (SULT) enzymes; glucuronidation by multiple glycosyltransferase (UGT) enzymes; N-demethylation catalyzed by multiple enzymes, including CYP2B6, CYP2C8, and CYP3A4/5; followed by conjugation. Metabolism of sublingual apomorphine results in three major inactive metabolites: apomorphine sulfate, apomorphine glucuronide, and norapomorphine glucuronide.

Excretion

Following sublingual administration of 15 mg of apomorphine, the geometric mean (CV%) of the apparent clearance was 1440 L/h (68%), and the geometric mean of the terminal elimination half-life is about 1.7 hours (range about 0.8 hour to 3 hours).

Specific Populations

The apparent clearance of apomorphine does not appear to be influenced by age, gender, race, weight, duration of Parkinson's disease, levodopa dose, use of antiemetic, or duration of therapy.

Renal Impairment

The clinical studies of KYNMOBI included patients with mild renal impairment (CLcr of ≥ 60 mL/min and <90 mL/min). There were no differences in apomorphine exposure after administration of KYNMOBI in patients with mild renal impairment as compared to patients with normal renal function (CLcr of ≥ 90 mL/min). Studies with KYNMOBI in patients with moderate to severe renal impairment have not been conducted.

In a study with subcutaneous apomorphine comparing patients with moderate renal impairment (as determined by estimated creatinine clearance) to healthy matched volunteers, the $AUC_{0-\infty}$ and C_{max}

values were increased by approximately 16% and 50%, respectively, following a single administration. The mean time to peak concentrations and the mean terminal half-life of apomorphine were unaffected by the renal status of the individual.

Since the C_{max} and $AUC_{0-\infty}$ of apomorphine following the sublingual administration are lower as compared to the subcutaneous route of administration and the KYNMOBI dose is titrated individually, these changes are not expected to be clinically significant for patients with mild or moderate renal impairment *[see Use in Specific Populations (8.6)]*.

Hepatic Impairment

Studies with KYNMOBI in patients with hepatic impairment have not been conducted.

In a study with subcutaneous apomorphine comparing patients with moderate hepatic impairment (as determined by the Child-Pugh classification method) to healthy matched volunteers, the $AUC_{0-\infty}$ and C_{max} values were increased by approximately 10% and 25%, respectively, following a single administration. These changes are not expected to be clinically significant for patients with mild or moderate hepatic impairment *[see Use in Specific Populations (8.7)]*.

Drug Interaction Studies

Carbidopa/levodopa

Levodopa pharmacokinetics were unchanged when subcutaneous apomorphine and levodopa were co-administrated in patients. However, motor response differences were significant. The threshold levodopa concentration necessary for an improved motor response was reduced significantly, leading to an increased duration of effect without a change in the maximal response to levodopa therapy.

Nitroglycerin

Co-administration of nitroglycerin (0.4 mg) with subcutaneous apomorphine in healthy subjects did not have a significant impact on the pharmacokinetics of apomorphine. However, concomitant administration of nitroglycerin (0.4 mg) with subcutaneous apomorphine caused greater decreases in blood pressure than with subcutaneous apomorphine alone *[see Warnings and Precautions (5.4) and Drug Interactions (7.2)]*.

When nitroglycerin and subcutaneous apomorphine were concomitantly administered to healthy subjects, the mean largest decrease (the mean of each subject's largest drop in blood pressure measured within the 6-hour period following administration of subcutaneous apomorphine) in supine systolic and diastolic blood pressure (measured over 6 hours) was 9.7 mm Hg and 9.3 mm Hg, respectively. The mean largest decrease in standing systolic and diastolic blood pressure was 14.3 mm Hg and 13.5 mm Hg, respectively. Some individuals experienced very large decreases in standing systolic and diastolic blood pressure, up to a maximum decrease of 65 mm Hg and 43 mm Hg, respectively. In comparison, the mean largest decrease in supine systolic and diastolic blood pressure when subcutaneous apomorphine was administered alone was 6.1 mm Hg and 7.3 mm Hg, respectively, and in standing systolic and diastolic blood pressure was 6.7 mm Hg and 8.4 mm Hg, respectively.

A similar study has not been performed with KYNMOBI.

Ethanol

Co-administration of low dose ethanol (0.3 g/kg) with subcutaneous apomorphine in healthy subjects did not have a significant impact on the pharmacokinetics of apomorphine, but high dose ethanol (0.6 g/kg), equivalent to approximately 3 standardized alcohol-containing beverages, increased the C_{max} of apomorphine by about 63%.

When high dose ethanol (0.6 g/kg) and subcutaneous apomorphine were concomitantly administered to healthy subjects, the mean largest decrease (the mean of each subject's largest drop in blood pressure measured within the 6-hour period following administration of subcutaneous apomorphine) for supine systolic and diastolic blood pressure was 9.1 mm Hg and 10.5 mm Hg, respectively. The mean largest standing systolic and diastolic blood pressure decrease was 11.3 mm Hg and 12.6 mm Hg, respectively.

In some individuals, the decrease was as high as 61 mm Hg and 51 mm Hg, respectively, for standing systolic and diastolic blood pressure.

When low dose ethanol (0.3 g/kg) and subcutaneous apomorphine were concomitantly administered, the mean largest decrease in supine systolic and diastolic blood pressure was 10.2 mm Hg and 9.9 mm Hg, respectively. The mean largest decrease in standing systolic and diastolic blood pressure was 8.4 mm Hg and 7.1 mm Hg, respectively. In comparison, the mean largest decrease in supine systolic and diastolic blood pressure when subcutaneous apomorphine was administered alone was 6.1 mm Hg and 7.3 mm Hg, respectively, and in standing systolic and diastolic blood pressure was 6.7 mm Hg 8.4 mm Hg, respectively.

A similar study has not been performed with KYNMOBI.

COMT Interactions

A pharmacokinetic interaction of apomorphine with catechol-O-methyl transferase (COMT) inhibitors or drugs metabolized by this route is unlikely since apomorphine appears not to be metabolized by COMT.

In vitro studies

Based on in vitro studies, the potential for KYNMOBI to interact with concomitant medications to cause a CYP metabolism or transporter-based drug-drug interaction is considered low.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Lifetime carcinogenicity studies of apomorphine were conducted in male (0.1, 0.3, or 0.8 mg/kg/day) and female (0.3, 0.8, or 2 mg/kg/day) rats. Apomorphine was administered by subcutaneous injection for 22 months or 23 months, respectively. In males, there was an increase in Leydig cell tumors at the highest dose tested. This finding is of questionable significance because the endocrine mechanisms believed to be involved in the production of Leydig cell tumors in rats are not relevant to humans. No drug-related tumors were observed in females.

In a 26-week carcinogenicity study in P53-knockout transgenic mice, there was no evidence of carcinogenic potential when apomorphine was administered by subcutaneous injection at doses up to 20 mg/kg/day (male) or 40 mg/kg/day (female).

Mutagenesis

Apomorphine was mutagenic in the in vitro bacterial reverse mutation (Ames) and the in vitro mouse lymphoma tk assays. Apomorphine was clastogenic in the in vitro chromosomal aberration assay in human lymphocytes and in the in vitro mouse lymphoma tk assay. Apomorphine was negative in the in vivo micronucleus assay in mice.

Impairment of Fertility

Apomorphine was administered subcutaneously at doses up to 3 mg/kg/day to male and female rats prior to and throughout the mating period and continuing in females through gestation day 6. There was no evidence of adverse effects on fertility or on early fetal viability. A significant decrease in testis weight was observed in a 39-week study in cynomolgus monkey at all subcutaneous doses tested (0.3, 1, or 1.5 mg/kg/day).

In a published fertility study, apomorphine was administered to male rats at subcutaneous doses of 0.2, 0.8, or 2 mg/kg prior to and throughout the mating period. Fertility was reduced at the highest dose tested.

14 CLINICAL STUDIES

The efficacy of KYNMOBI for the acute, intermittent treatment of “off” episodes in patients with Parkinson's disease was established in one randomized, double-blind, placebo-controlled, parallel-group study (Study 1; NCT02469090).

The study enrolled patients with a mean duration of Parkinson's disease of approximately 9 years (range: 2 years to 22 years) who were Hoehn and Yahr Stage III or less in the “on” state, and who were all receiving concomitant levodopa with a stable dose for at least 4 weeks before screening. The most commonly used concomitant Parkinson's disease medications in addition to levodopa were oral dopaminergic agonists (51%), monoamine oxidase B inhibitors (41%), amantadine derivatives (21%), and other dopaminergic agents (8%).

At baseline, the mean number of daily “off” episodes was 4 and the mean duration of “off” episodes was slightly over an hour in both groups. The study included a titration phase and a 12-week maintenance phase. Patients were titrated to the dose that achieved a full “on” response and was tolerated during the titration phase. Patients were treated with an oral antiemetic starting 3 days before the titration phase. In the titration phase, patients (N=141) arrived at the study site in an “off” state having not taken their regular morning dose of carbidopa/levodopa or any other adjunctive PD medications, as well as having taken their last dose of carbidopa/levodopa and any other adjunctive PD medications no later than midnight the night before. Treatment was initiated in the clinic with a 10 mg dose of KYNMOBI. If the patient responded to treatment and tolerated the 10 mg KYNMOBI dose, the patient was randomized in a blinded fashion to KYNMOBI or placebo in a 1:1 ratio. If the patient tolerated the dose but did not adequately respond, the patient was asked to return to the clinic within 3 days and the dose was increased by 5 mg. The titration process was continued up to a maximum KYNMOBI dose of 35 mg or until a full “on” was achieved as determined by the investigator and the patient *[see Dosage and Administration (2.2)]*. Dose administration was permitted up to five times per day in the maintenance phase. The Movement Disorder Society-Unified Parkinson's Disease Rating Scale, Part III (MDS-UPDRS III) (motor examination) was measured pre dose, and at 15, 30, 45, 60, and 90 minutes post dose.

The primary endpoint of the study was the mean change from pre dose to 30 minutes post dose in the MDS-UPDRS III at the 12-week visit of the maintenance phase.

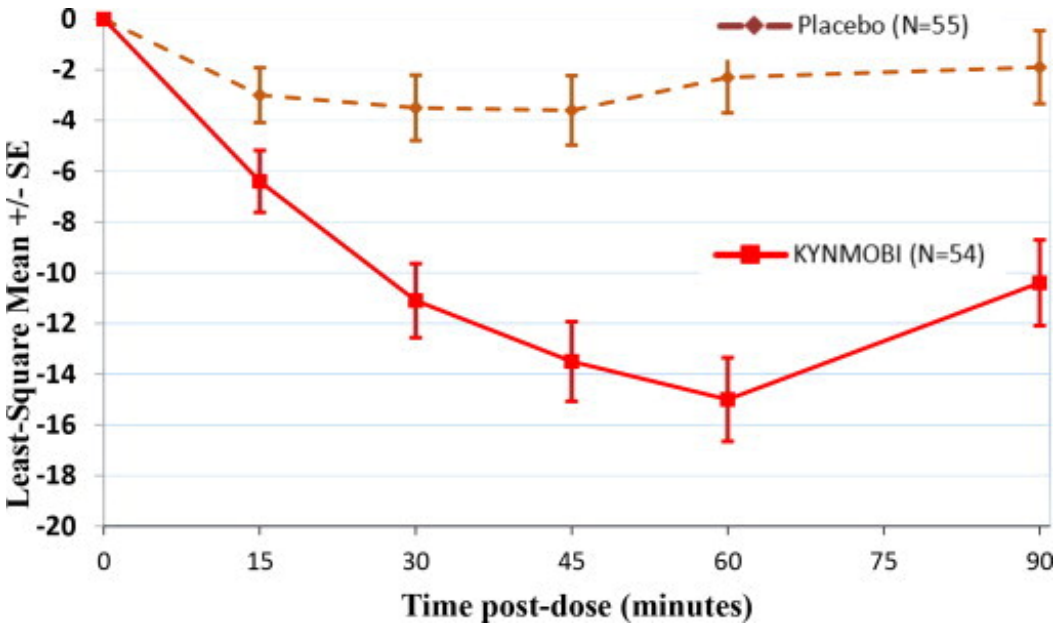
A total of 54 patients were randomized to KYNMOBI and 55 patients to placebo. The KYNMOBI treatment group showed a least-square mean improvement (i.e., reduction in score) of -11.1 points (95% CI: -14.0, -8.2), versus -3.5 points for the placebo group (95% CI: -6.1, -0.9). The least-square mean treatment difference between KYNMOBI and placebo was -7.6 (95% CI: -11.5, -3.7; p = 0.0002) (Table 2).

Table 2: Change from Pre-dose to 30 Minutes Post-dose in the MDS-UPDRS III Score at Week 12 (Least-Square Mean) in Study 1

Treatment	Number of Patients at Week 12	Observed Pre-dose MDS-UPDRS III Score at Week 12	Least-Square Mean Change from Pre-dose to 30 Minutes Post-dose	Least-Square Mean Difference from placebo
Placebo	46	42.2	- 3.5	N/A
KYNMOBI	34	37.2	- 11.1	- 7.6 (p=0.0002)

Figure 2 describes the least-square mean change from pre-dose in MDS-UPDRS Part III Motor Scores after administration of KYNMOBI versus placebo at week 12.

Figure 2: Estimated Least-Square Mean Change in MDS-UPDRS Part III Motor Score After Administration of KYNMOBI vs. Placebo (at Week 12) in Study 1



16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

KYNMOBI sublingual film is a blue to green rectangular film with a white printed number identifying the strength (e.g., "10" is 10 mg). Each sublingual film is individually packaged in a sealed foil pouch. Films are supplied in the following strengths and package configurations (Table 3):

Table 3: Package Configuration for KYNMOBI sublingual film

Single Film Strength (NDC Code)	Package Configuration	NDC Code
Trade Titration Kit		
10 mg (63402-010-01) 15 mg (63402-015-01) 20 mg (63402-020-01) 25 mg (63402-025-01) 30 mg (63402-030-01)	Each titration kit carton will contain a total of 10 individually packaged films of: 2 – single 10 mg films 2 – single 15 mg films 2 – single 20 mg films 2 – single 25 mg films 2 – single 30 mg films	63402-088-10
Trade Product		
10 mg (63402-010-01)	30 films per carton	63402-010-30
15 mg (63402-015-01)	30 films per carton	63402-015-30
20 mg (63402-020-01)	30 films per carton	63402-020-30
25 mg (63402-025-01)	30 films per carton	63402-025-30
30 mg (63402-030-01)	30 films per carton	63402-030-30

16.2 Storage and Handling

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP controlled room temperature].

Keep KYNMOBI in the foil pouch until ready to use.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information and Instructions for Use).

Administration of KYNMOBI

Advise patients that KYNMOBI is for sublingual use only *[see Dosage and Administration (2.1)]*.

KYNMOBI must be administered whole. Advise patients not to cut, chew, or swallow KYNMOBI.

Nausea and Vomiting

Advise patients that KYNMOBI may cause nausea and vomiting when it is administered at recommended doses. Treatment with an antiemetic (e.g., trimethobenzamide) may be used, as needed, if nausea or vomiting occurs. Inform patients that they should discuss with their healthcare provider when the antiemetic can be discontinued *[see Warnings and Precautions (5.1)]*.

Falling Asleep During Activities of Daily Living and Somnolence

Alert patients to the potential sedating effects of KYNMOBI, including somnolence and falling asleep while engaged in activities of daily living. Instruct patients not to drive a car or engage in other potentially dangerous activities until they have gained sufficient experience with KYNMOBI to gauge whether or not it affects their mental and/or motor performance adversely. Advise patients that if increased somnolence or episodes of falling asleep during activities of daily living (e.g., watching television, passenger in a car, etc.) occur, they should not drive or participate in potentially dangerous activities until they have discussed this with their healthcare provider. Because of possible additive effects of alcohol use, advise patients to limit their alcohol intake *[see Warnings and Precautions (5.2)]*.

Hypersensitivity / Allergic Reactions

Advise patients that hypersensitivity/allergic reaction (e.g., swelling of the lips, tongue and mouth, flushing, and, infrequently, urticaria and throat tightness) may occur because of apomorphine, sodium metabisulfite, or any KYNMOBI excipients. Inform patients with a sulfite sensitivity that KYNMOBI contains sodium metabisulfite, a sulfite that may cause allergic-type reactions, including anaphylactic symptoms and life-threatening or less severe asthmatic episodes *[see Warnings and Precautions (5.3)]*. Advise patients who experience any hypersensitivity/allergic reaction to KYNMOBI that they should avoid taking KYNMOBI again *[see Contraindications (4)]*.

Hypotension/Orthostatic Hypotension

Advise patients that they may develop postural (orthostatic) hypotension with or without symptoms, such as dizziness, nausea, syncope, and sweating. Instruct patients to rise slowly after sitting or lying down after taking KYNMOBI. Instruct patients to limit their alcohol intake because it may potentiate the hypotensive effect of KYNMOBI. Instruct patients to lie down before and after taking sublingual nitroglycerin because it may potentiate the hypotensive effect of KYNMOBI *[see Warnings and Precautions (5.4)]*.

Oral Mucosal Irritation

Inform patients that KYNMOBI may result in oral mucosal adverse reactions such as irritation, erythema, lip swelling, mouth ulceration, dry mouth, stomatitis, glossodynia, oropharyngeal pain, swollen tongue, ageusia, oral pain, lip ulceration, oral disorder and hypoaesthesia oral *[see Warnings and Precautions (5.5) and Adverse Reactions (6.1)]*.

Falls

Alert patients that they may have increased risk for falling when using KYNMOBI *[see Warnings and Precautions (5.6)]*.

Hallucinations and/or Psychotic-Like Behavior

Inform patients that KYNMOBI may cause hallucinations or other manifestations of psychotic-like behavior. Advise patients to inform their healthcare provider if they have a major psychotic disorder or

are taking any treatments for psychosis *[see Warnings and Precautions (5.7)]*.

Impulse Control / Compulsive Behaviors

Patients and their caregivers should be alerted to the possibility that they may experience intense urges to spend money uncontrollably, intense urges to gamble, increased sexual urges, binge eating and/or other intense urges and the inability to control these urges while taking KYNMOBI *[see Warnings and Precautions (5.8)]*.

Withdrawal-Emergent Hyperpyrexia and Confusion

Advise patients to contact their healthcare provider if they wish to discontinue KYNMOBI or decrease the dose of KYNMOBI *[see Warnings and Precautions (5.9)]*.

QTc Prolongation and Potential for Proarrhythmic Effects

Alert patients that KYNMOBI may cause QTc prolongation and might produce proarrhythmic effects that could cause torsades de pointes and sudden death. Palpitations and syncope may signal the occurrence of an episode of torsades de pointes *[see Warnings and Precautions (5.10)]*.

Priapism

Advise patients that KYNMOBI may cause prolonged painful erections and that if this occurs that they should seek medical attention immediately *[see Warnings and Precautions (5.12)]*.

Manufactured for:
Sunovion Pharmaceuticals Inc.
Marlborough, Massachusetts 01752 USA

For more information, go to www.KYNMOBI.com or call Sunovion Customer Service at 1-888-394-7377.

10413-01

Patient Information
KYNMOBI™ (kin-moe′-bee)
(apomorphine hydrochloride)
sublingual film

Read this Patient Information before you start taking KYNMOBI and each time you get a refill. There may be new information. This Patient Information does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is KYNMOBI?
KYNMOBI is a prescription medicine used to treat short-term (acute), intermittent “off” episodes in people with Parkinson's disease (PD).
It is not known if KYNMOBI is safe and effective in children.

Do not take KYNMOBI if you are:

- taking certain medicines to treat nausea called 5HT3 antagonists including ondansetron, granisetron, dolasetron, palonosetron, and alosetron. People taking ondansetron together with apomorphine, the active ingredient in KYNMOBI, have had very low blood pressure and lost consciousness or “blacked out.”
- allergic to apomorphine hydrochloride or to any of the ingredients in KYNMOBI. See the end of the Patient Information leaflet for a complete list of ingredients in KYNMOBI.

KYNMOBI also contains a sulfite called sodium metabisulfite. Sulfites can cause severe, life-threatening allergic reactions in some people. An allergy to sulfites is not the same as an allergy to sulfa. People with asthma are more likely to be allergic to sulfites.

Call your healthcare provider or get emergency help right away if you get any of the following symptoms of a severe life-threatening allergic reaction:

- hives
- itching
- rash
- swelling of the lips, tongue, and mouth
- redness of your face (flushing)
- throat tightness
- trouble breathing or swallowing

Before you start taking KYNMOBI, tell your healthcare provider about all of your medical conditions, including if you:

- have difficulty staying awake during the daytime.
- have dizziness.
- have fainting spells.
- have low blood pressure.
- have asthma.
- are allergic to any medicines containing sulfites
- have liver problems.
- have kidney problems.
- have heart problems.
- have had a stroke or other brain problems.
- have a mental problem called a major psychotic disorder.
- drink alcohol.
- are pregnant or plan to become pregnant. It is not known if KYNMOBI will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if KYNMOBI passes into your breast milk. You and your healthcare provider should decide if you will take KYNMOBI or breastfeed.
- **Tell your healthcare provider about all the medicines you take**, including prescription medicines and, over-the-counter medicines, vitamins, and herbal supplements.

KYNMOBI may affect the way other medicines work, and other medicines can affect how KYNMOBI works.

Taking KYNMOBI with other medicines may cause serious side effects.

- If you take nitroglycerin under your tongue (sublingual) while using KYNMOBI, your blood pressure may decrease and cause dizziness. You should lie down before and after taking sublingual nitroglycerin.

Know the medicines you take. Keep a list of your medicines with you and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take KYNMOBI?

- **Read the step-by-step Instructions for Use that comes with your KYNMOBI prescription.**
- **Take KYNMOBI exactly as your healthcare provider tells you to take it.**
- Your healthcare provider will tell you how much KYNMOBI to take and teach you the right way to take it.
- Your healthcare provider may change your dose if needed.
- **Do not** change your dose of KYNMOBI or take it more often than prescribed unless your healthcare provider has told you to.
- **Do not** take more than 1 dose of KYNMOBI to treat a “OFF” episode.
- **Do not** take another dose of KYNMOBI sooner than 2 hours after the last dose.
- **Do not** take KYNMOBI more than 5 times a day.
- **Do not** cut, chew or swallow KYNMOBI.

- Your healthcare provider may prescribe another medicine for nausea called an antiemetic to take while you are taking KYNMOBI. Antiemetic medicines help to decrease the symptoms of nausea and vomiting that can happen when you take KYNMOBI.

What should I avoid while taking KYNMOBI?

- **Do not** drink alcohol while you are taking KYNMOBI. It can increase your chance of developing serious side effects.
- **Do not** take medicines that make you sleepy while you are using KYNMOBI.
- **Do not** drive, operate machinery, or do other dangerous activities until you know how KYNMOBI affects you.
- **Do not** change your body position too fast. Get up slowly from sitting or lying. KYNMOBI can lower your blood pressure and cause dizziness or fainting.

What are the possible side effects of KYNMOBI?

KYNMOBI can cause serious side effects, including:

- **nausea and vomiting. Nausea is a common side effect of KYNMOBI**. Nausea and vomiting can happen with KYNMOBI. Your healthcare provider may prescribe a medicine called an antiemetic, such as trimethobenzamide, to help prevent nausea and vomiting. Some patients can stop taking trimethobenzamide after using KYNMOBI, when advised by your healthcare provider. Some patients may need to keep taking trimethobenzamide to help treat nausea and vomiting. Talk to your healthcare provider before you stop taking trimethobenzamide.
- **sleepiness or falling asleep during the day. Sleepiness is a serious and common side effect of KYNMOBI.** Some people treated with KYNMOBI may get sleepy during the day or fall asleep without warning while doing everyday activities such as talking, eating, or driving a car.
- **allergic reactions.** See the "**Do not take KYNMOBI if you are**" section.
- **dizziness. Dizziness is a serious, and common side effect of KYNMOBI**. KYNMOBI may lower your blood pressure and cause dizziness. Dizziness can happen when KYNMOBI treatment is started or when the KYNMOBI dose is increased. Do not get up too fast from sitting or after lying down, especially if you have been sitting or lying down for a long period of time.
- **mouth (oral) irritation. Mouth (oral) irritation is a common side effect of KYNMOBI**. You should call your healthcare provider if you develop any of these signs or symptoms:

  - redness
  - swelling
  - mouth sores (ulceration)
  - pain
  - dryness of the mouth, lips or tongue
  - pain with swallowing

These signs and symptoms may go away if KYNMOBI treatment is stopped.

- **falls.** The changes that can happen with PD, and the effects of some PD medicines, can increase the risk of falling. KYNMOBI may also increase your risk of falling.
- **hallucinations or psychotic-like behavior.** KYNMOBI may cause or make psychotic-like behavior worse including hallucinations (seeing or hearing things that are not real), confusion, excessive suspicion, aggressive behavior, agitation, delusional beliefs (believing things that are not real), and disorganized thinking.
- **strong (intense) urges.** Some people with PD have reported new or strong uncontrollable urges to gamble, increased sexual urges, increased urges to spend money (compulsive shopping), and other intense urges, while taking PD medicines, including KYNMOBI. If you or your family members notice that you have strong urges, talk to your healthcare provider. The strong urges may go away if your KYNMOBI dose is lowered or stopped.
- **high fever and confusion.** KYNMOBI may cause a problem that can happen in people who suddenly lower their dose, stop using, or change their dose of KYNMOBI. Symptoms include:

  - very high fever
  - confusion

- stiff muscles
- changes in breathing and heartbeat

Do not stop taking KYNMOBI or change your dose unless you are told to do so by your healthcare provider.

- **heart problems.** If you have shortness of breath, fast heartbeat, chest pain, or feel like you are going to pass out (faint) while taking KYNMOBI, call your healthcare provider or get emergency help right away.
- **tissue changes (fibrotic complications).** Some people have had changes in the tissues of their pelvis, lungs, and heart valves when taking medicines called nonergot derived dopamine agonists like KYNMOBI.
- **prolonged painful erections (priaprism).** KYNMOBI may cause prolonged, painful erections in some people. If you have a prolonged and painful erection you should call your healthcare provider or go to the nearest hospital emergency room right away.

If you have any of these symptoms, stop taking KYNMOBI and call your healthcare provider right away before
taking another dose.

The most common side effects of KYNMOBI include:

- nausea
- sleepiness
- dizziness
- mouth swelling, pain, or sores

These are not all of the possible side effects of KYNMOBI.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store KYNMOBI?

- Store KYNMOBI at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep KYNMOBI in the foil pouch until you are ready to take it.

Keep KYNMOBI and all medicines out of the reach of children.

General information about the safe and effective use of KYNMOBI.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use KYNMOBI for a condition for which it was not prescribed. Do not give KYNMOBI to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about KYNMOBI that is written for health professionals.

What are the ingredients in KYNMOBI?

Active ingredient: apomorphine hydrochloride

Inactive ingredients: disodium EDTA, dihydrate, FD&C Blue #1, glycerol, glyceryl monostearate, hydroxyethyl cellulose, hypromellose, maltodextrin, (-)-menthol, pyridoxine hydrochloride, sodium hydroxide, sodium metabisulfite, sucralose, and white ink.

sunovion

Manufactured for:
Sunovion Pharmaceuticals Inc.
Marlborough, Massachusetts 01752 USA

For more information, go to www.KYNMOBI.com or call Sunovion Customer Service at 1-888-394-

7377.
10413-01

This Patient Information has been approved by the U.S. Food and Drug Administration Issued: 5/2020

INSTRUCTIONS FOR USE
KYNMOBI™ (kin-moe′-bee)
(apomorphine hydrochloride)
Sublingual Film

Read this Instructions for Use before you start taking KYNMOBI and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

Important

- KYNMOBI is for sublingual (under your tongue) use only.
- KYNMOBI must be taken whole. **Do not** cut, chew, or swallow KYNMOBI.
- **Do not take** KYNMOBI until you talk with your healthcare provider about how to take it.
- Check the expiration date printed on the foil pouch. **Do not** use KYNMOBI if the expiration date has passed.
- **Do not** take more than 1 dose of KYNMOBI every 2 hours.
- **Do not** take more than 5 doses of KYNMOBI each day.

How to store KYNMOBI

- Store KYNMOBI at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep KYNMOBI in the foil pouch until you are ready to take it.
- **Keep KYNMOBI and all medicines out of the reach of children.**

How KYNMOBI is packaged

Inside each child-resistant carton is a plastic tray with a pull-out handle that holds the sealed pouches of KYNMOBI sublingual film (see **Figure A**). Each KYNMOBI sublingual film comes in a sealed foil pouch (see **Figure B**).

Figure A

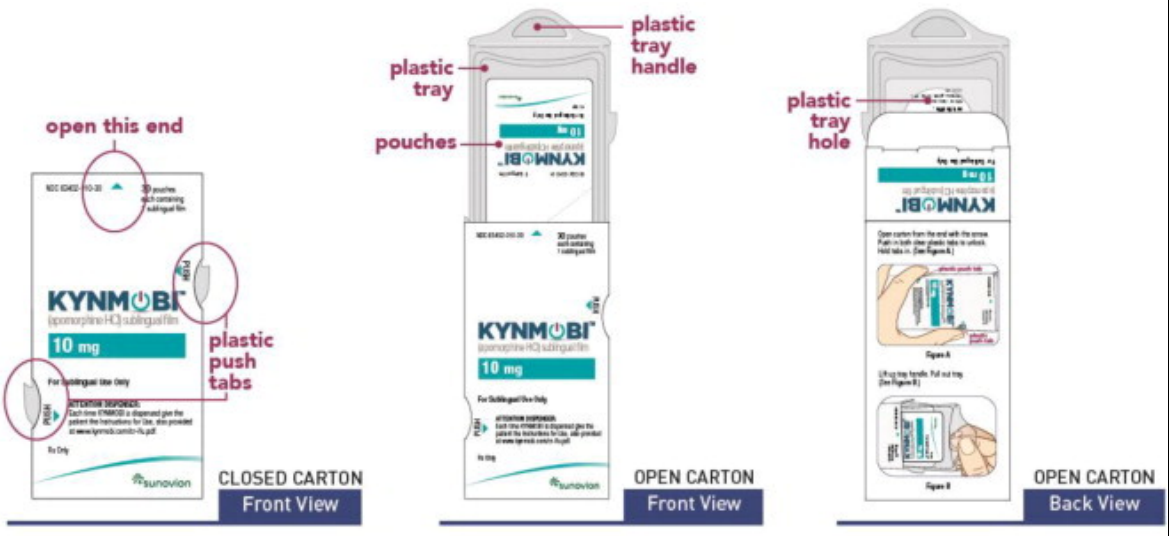
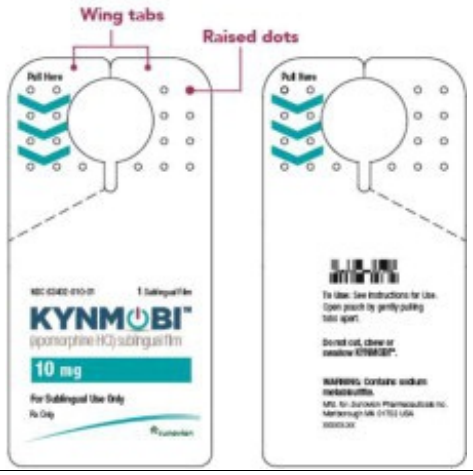


Figure B



ATTENTION: Read the Instructions for Use on the other side of this leaflet.

sunovion

INSTRUCTIONS FOR USE

Instructions on How to Use the Child-Resistant Carton

STEP 1 Open Carton

Open carton from the end with the arrow. Push in both tabs to unlock. Hold tabs in. (See **Figure C**.)

Lift up tray handle. Pull out tray (see **Figure D**).

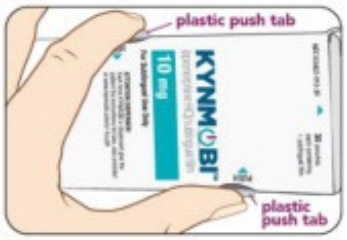


Figure C

Figure D

STEP 2 Remove Pouch

Push finger up through the hole in the bottom of tray. (See **Figure E**.)

Firmly pull one (1) pouch from the tray (see **Figure F**).

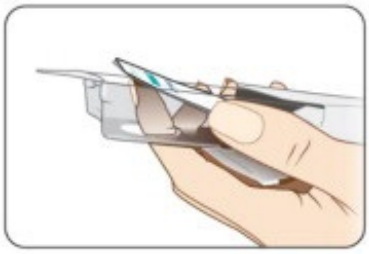


Figure E

Figure F

STEP 3 Close Carton

To close, slide tray in until it clicks. (See **Figure G**.)

This ensures the carton remains child resistant (see **Figure H**).

Figure G

Figure H

Instructions for Taking KYNMOBI

Step 4

- Your healthcare provider has told you to take KYNMOBI 10 mg, 15 mg, 20 mg, 25 mg, or 30 mg. Complete Steps 5 through

Step 5

Drink water. Before taking each KYNMOBI, drink water to moisten your mouth.

This helps the film dissolve more easily (see **Figure I**).

Step 6

Open the KYNMOBI foil pouch.

Hold the wing tabs on the pouch between your thumb and pointer finger of each hand. Make sure to place your fingers directly on the raised

Step 7

Take KYNMOBI out of the pouch.

Hold KYNMOBI between your fingers by the outside edges and remove the entire KYNMOBI from the pouch (see Figure K).

KYNMOBI must be taken

10 to take KYNMOBI.

Figure I

dots on each wing tab. Gently pull the wing tabs apart to open the pouch (see **Figure J**).

Figure J

whole. Throw away KYNMOBI if it is broken or missing pieces. Use a new KYNMOBI for your dose.

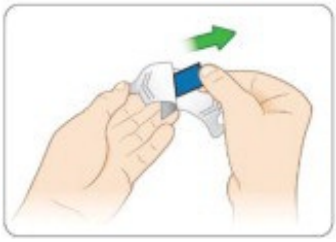


Figure K

Step 8
Place entire KYNMOBI under your tongue. Place KYNMOBI as far back under your tongue as you can (see **Figure L**).
Close your mouth.

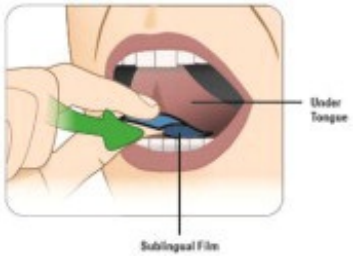


Figure L

Step 9
Keep KYNMOBI in place until it has completely dissolved (see **Figure M**).

- **Do not** chew or swallow KYNMOBI.
- **Do not** swallow your saliva or talk while KYNMOBI is dissolving because this can affect how well the medicine in KYNMOBI is absorbed.

Figure M

Step 10
Open your mouth to check if KYNMOBI has completely dissolved.
It can take **about 3 minutes** for KYNMOBI to dissolve. After the film completely dissolves, you may swallow.

For assistance with the KYNMOBI child-resistant carton, please ask your care partner for help.
You may also contact your doctor or Sunovion Customer Service at 1-888-394-7377 with questions or for support.
This Instructions for Use has been approved by the U.S. Food and Drug Administration.
Manufactured for Sunovion Pharmaceuticals Inc. Marlborough, Massachusetts 01752 USA.

Issued 5/2020
10414-01

(*See reverse side for additional information*)

PRINCIPAL DISPLAY PANEL – TRADE POUCH LABEL – 10 mg

NDC 63402-010-01 1 sublingual film

Apomorphine HCl

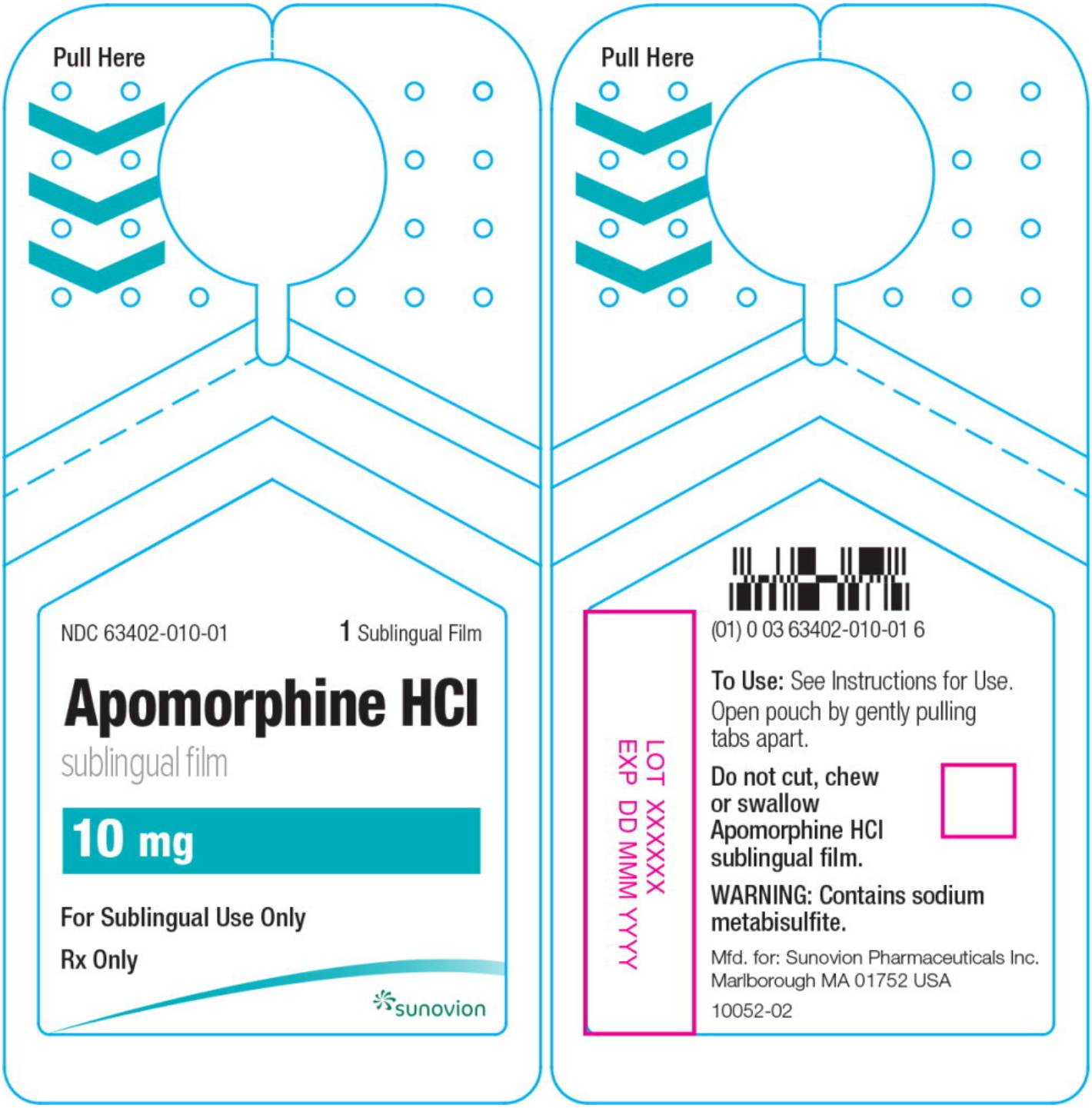
sublingual film

10 mg

For Sublingual Use Only

Rx only

SUNOVION



PRINCIPAL DISPLAY PANEL – TRADE POUCH LABEL – 15 mg

NDC 63402-015-01 1 sublingual film

Apomorphine HCl

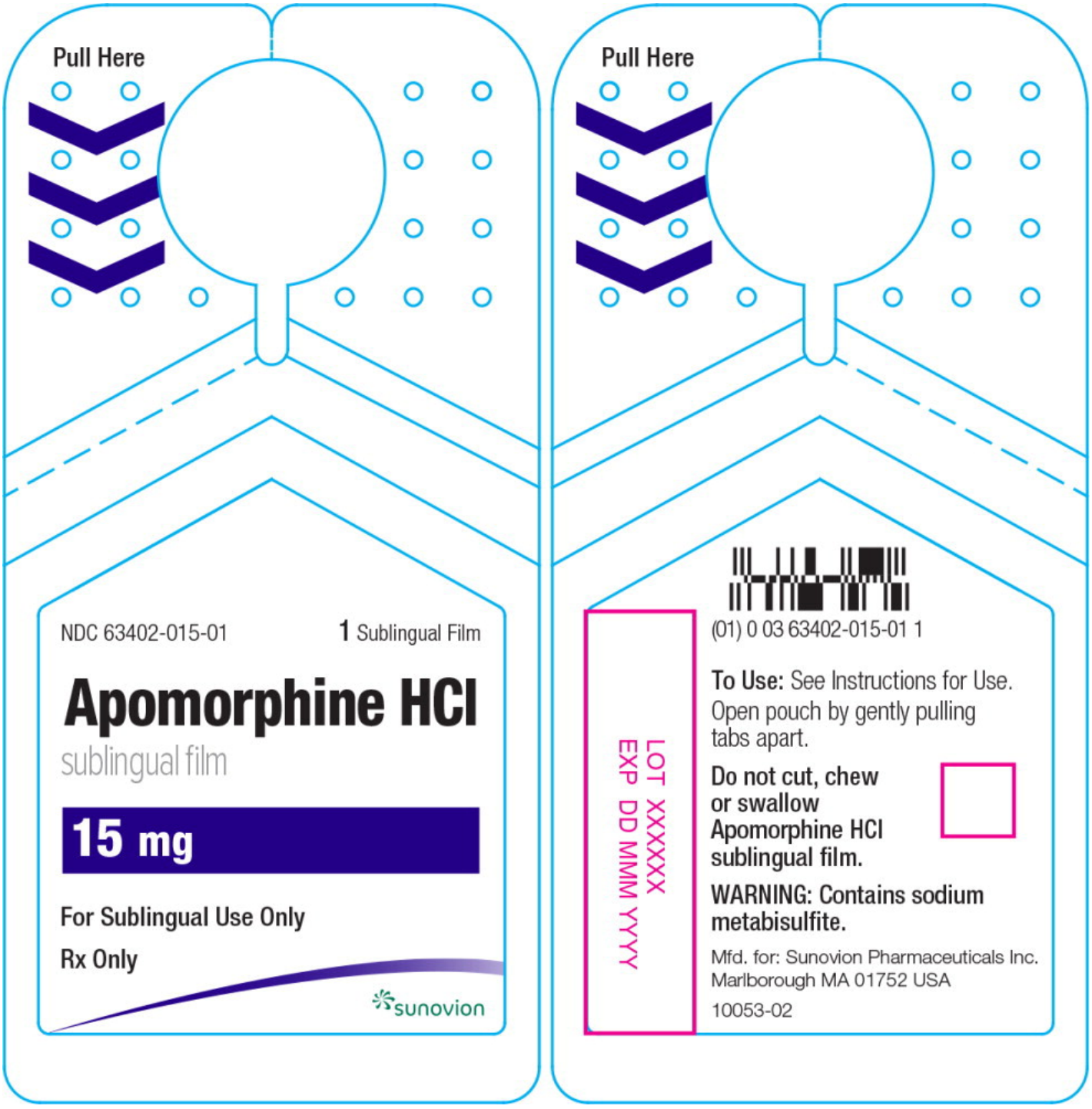
sublingual film

15 mg

For Sublingual Use Only

Rx only

SUNOVION



PRINCIPAL DISPLAY PANEL – TRADE POUCH LABEL – 20 mg

NDC 63402-020-01 1 sublingual film

Apomorphine HCl

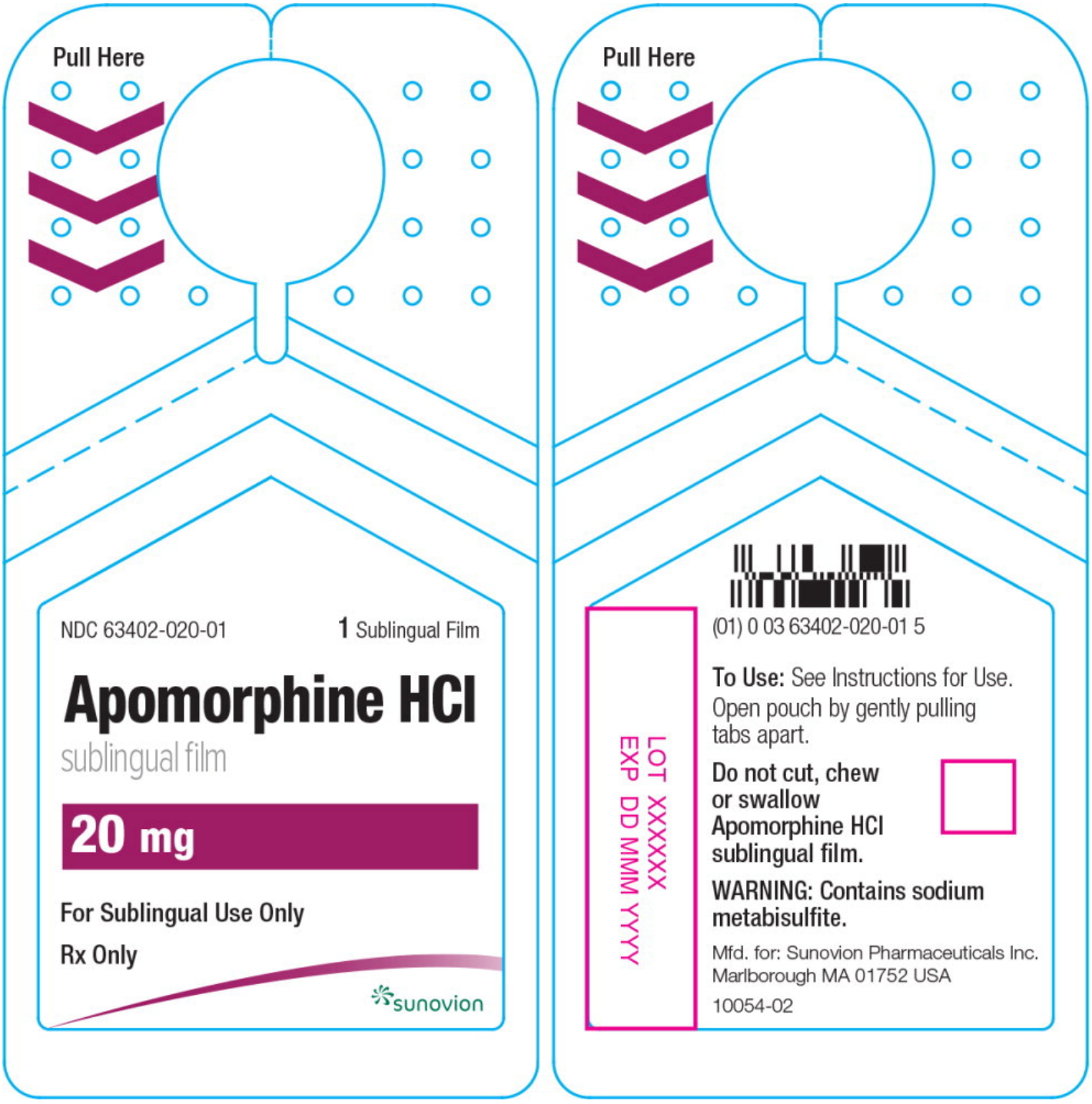
sublingual film

20 mg

For Sublingual Use Only

Rx only

SUNOVION



PRINCIPAL DISPLAY PANEL – TRADE POUCH LABEL – 25 mg

NDC 63402-025-01 1 sublingual film

Apomorphine HCl

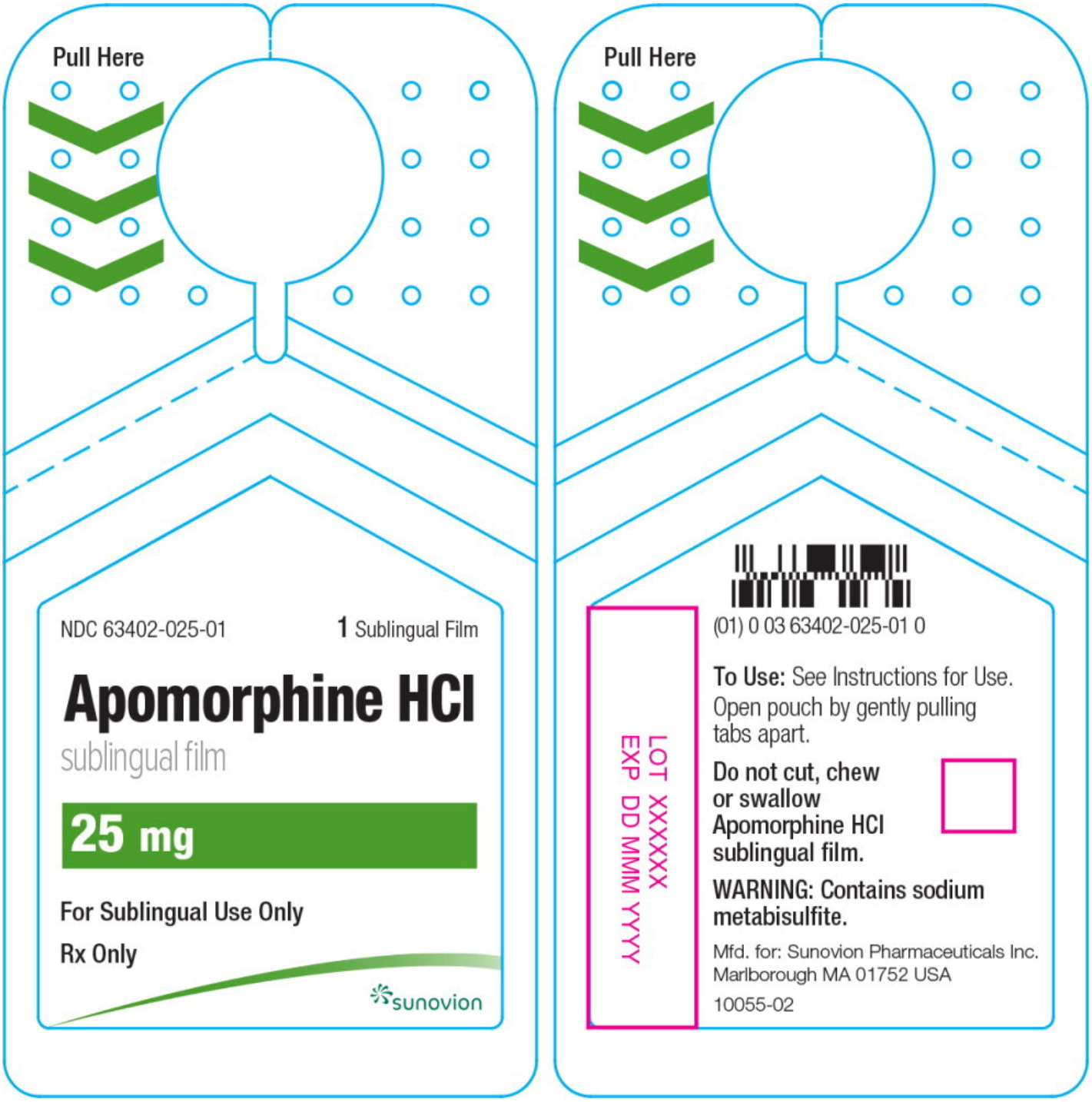
sublingual film

25 mg

For Sublingual Use Only

Rx only

SUNOVION



PRINCIPAL DISPLAY PANEL – TRADE POUCH LABEL – 30 mg

NDC 63402-030-01 1 sublingual film

Apomorphine HCl

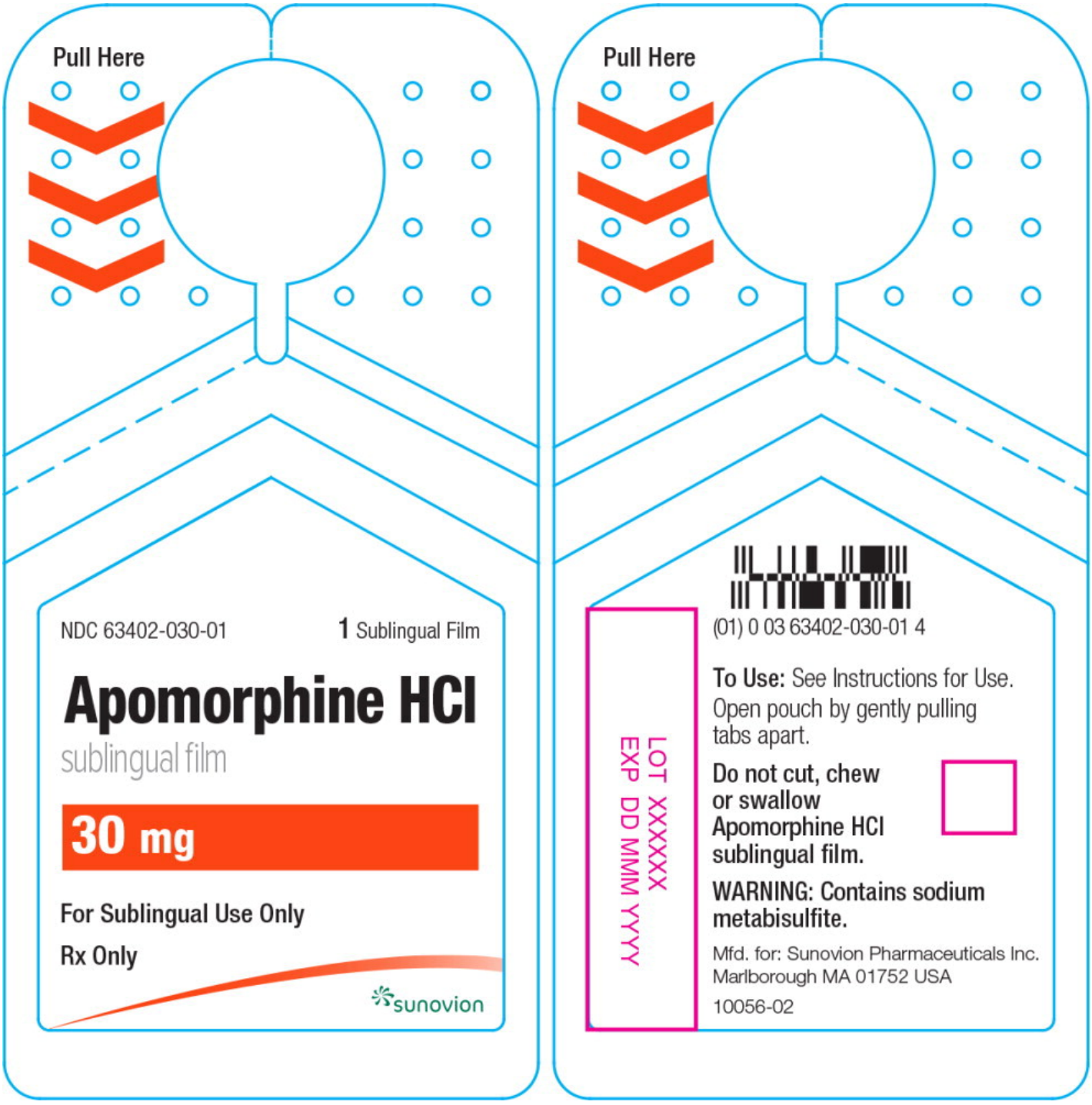
sublingual film

30 mg

For Sublingual Use Only

Rx only

SUNOVION



PRINCIPAL DISPLAY PANEL – TRADE CARTON – 10 mg

NDC 63402-010-30 30 pouches each containing 1 sublingual film

KYNMOBI™

(apomorphine HCl) sublingual film

10 mg

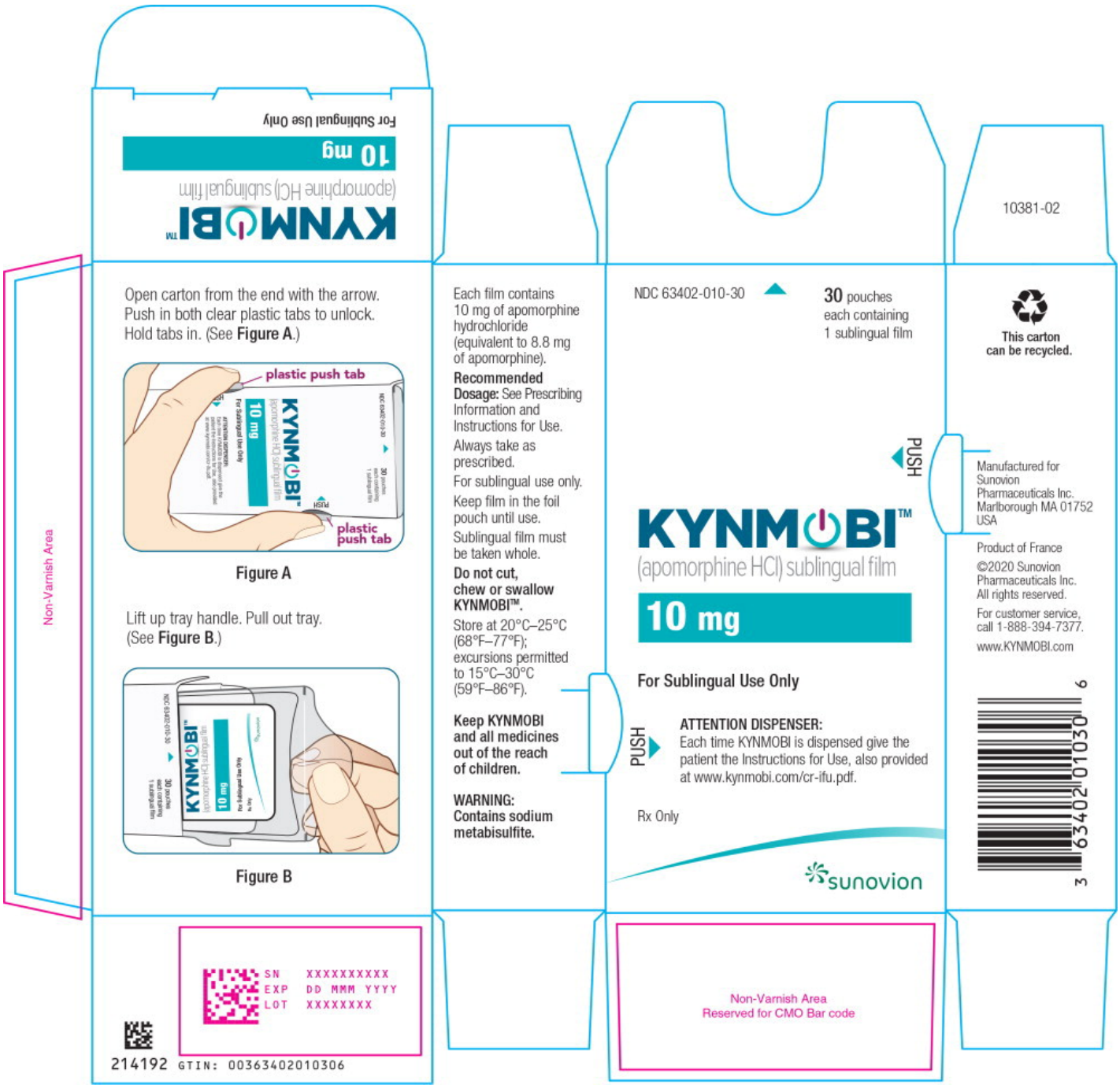
For Sublingual Use Only

ATTENTION DISPENSER:

Each time KYNMOBI is dispensed give the patient the Instructions for Use, also provided at www.kynmobi.com/cr-ifu.pdf

Rx only

SUNOVION



PRINCIPAL DISPLAY PANEL – TRADE CARTON – 15 mg

NDC 63402-015-30 30 pouches each containing 1 sublingual film

KYNMOBI™

(apomorphine HCl) sublingual film

15 mg

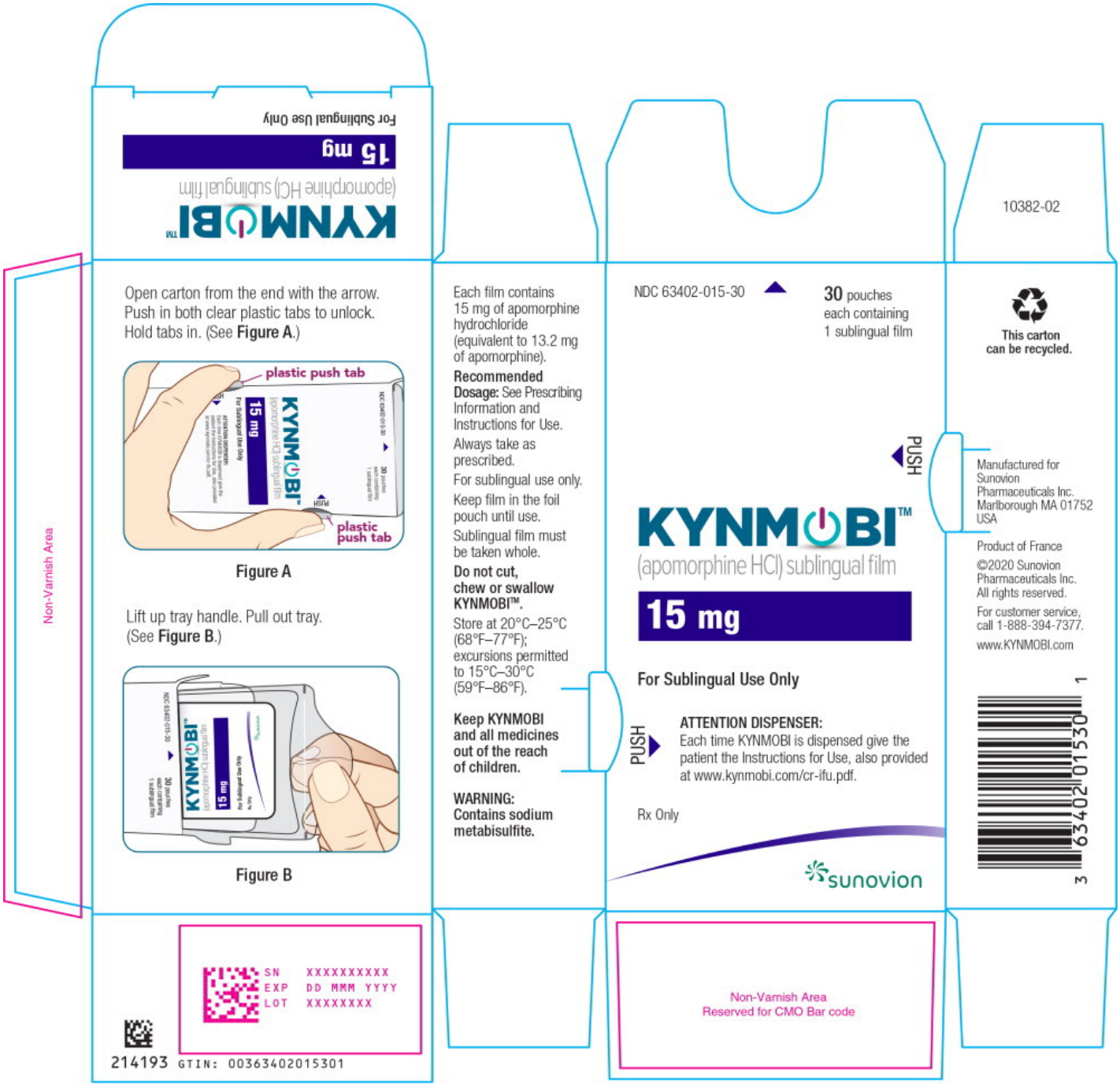
For Sublingual Use Only

ATTENTION DISPENSER:

Each time KYNMOBI is dispensed give the patient the Instructions for Use, also provided at www.kynmobi.com/cr-ifu.pdf

Rx only

SUNOVION



PRINCIPAL DISPLAY PANEL – TRADE CARTON – 20 mg

NDC 63402-020-30 30 pouches each containing 1 sublingual film

KYNMOBI™

(apomorphine HCl) sublingual film

20 mg

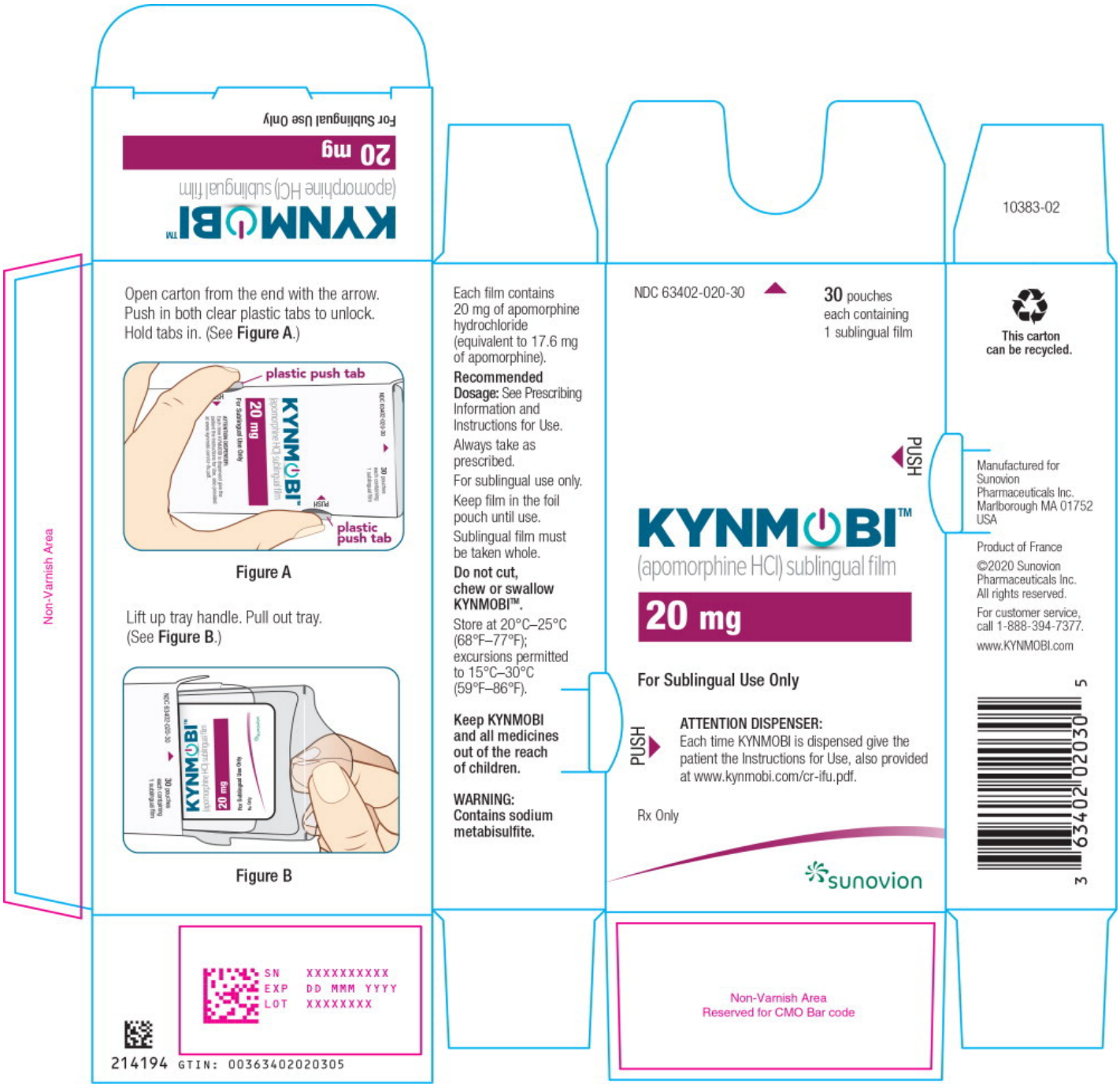
For Sublingual Use Only

ATTENTION DISPENSER:

Each time KYNMOBI is dispensed give the patient the Instructions for Use, also provided at www.kynmobi.com/cr-ifu.pdf

Rx only

SUNOVION



PRINCIPAL DISPLAY PANEL – TRADE CARTON – 25 mg

NDC 63402-025-30 30 pouches each containing 1 sublingual film

KYNMOBI™

(apomorphine HCl) sublingual film

25 mg

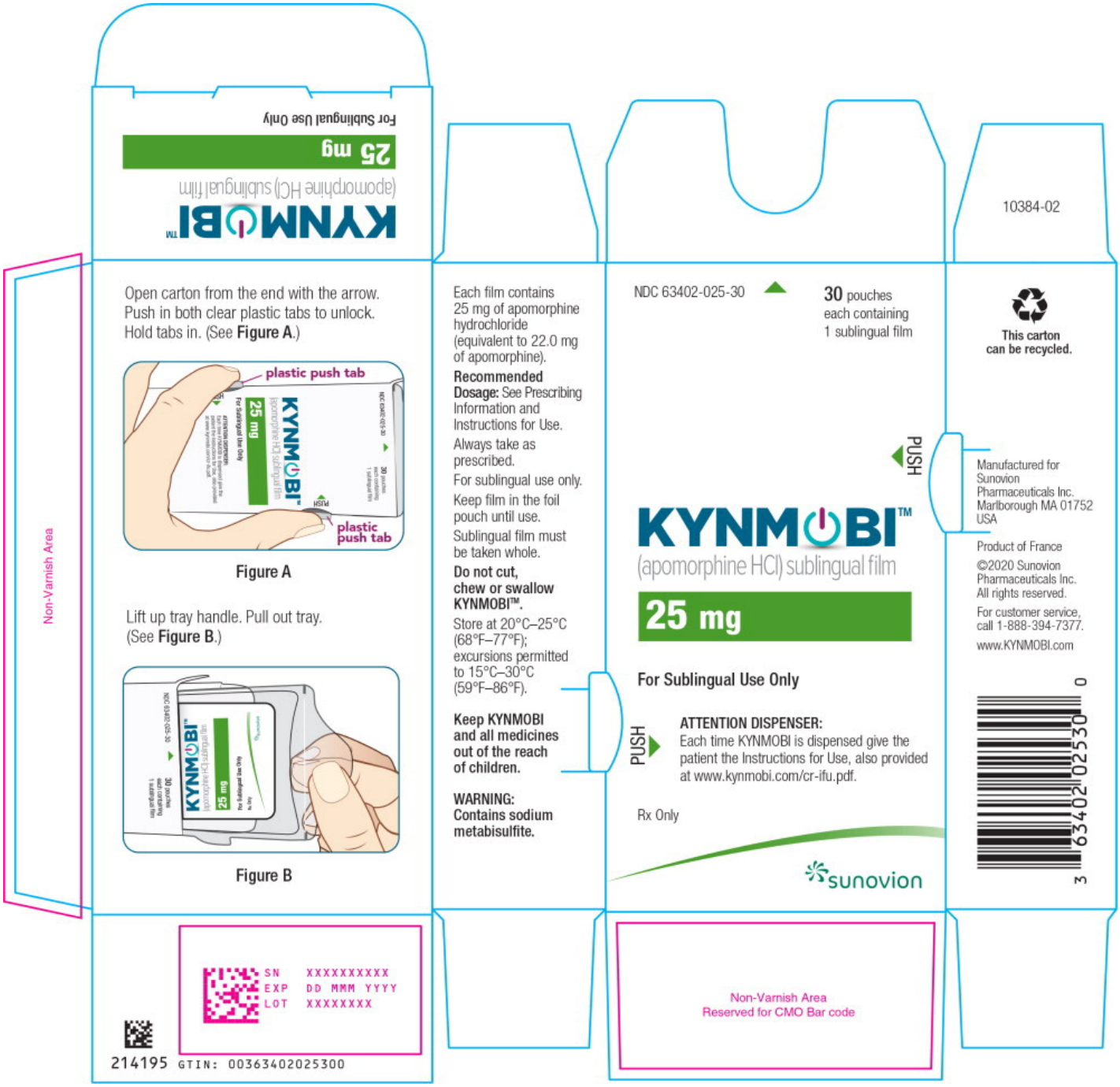
For Sublingual Use Only

ATTENTION DISPENSER:

Each time KYNMOBI is dispensed give the patient the Instructions for Use, also provided at www.kynmobi.com/cr-ifu.pdf

Rx only

SUNOVION



PRINCIPAL DISPLAY PANEL – TRADE CARTON – 30 mg

NDC 63402-030-30 30 pouches each containing 1 sublingual film

KYNMOBI™

(apomorphine HCl) sublingual film

30 mg

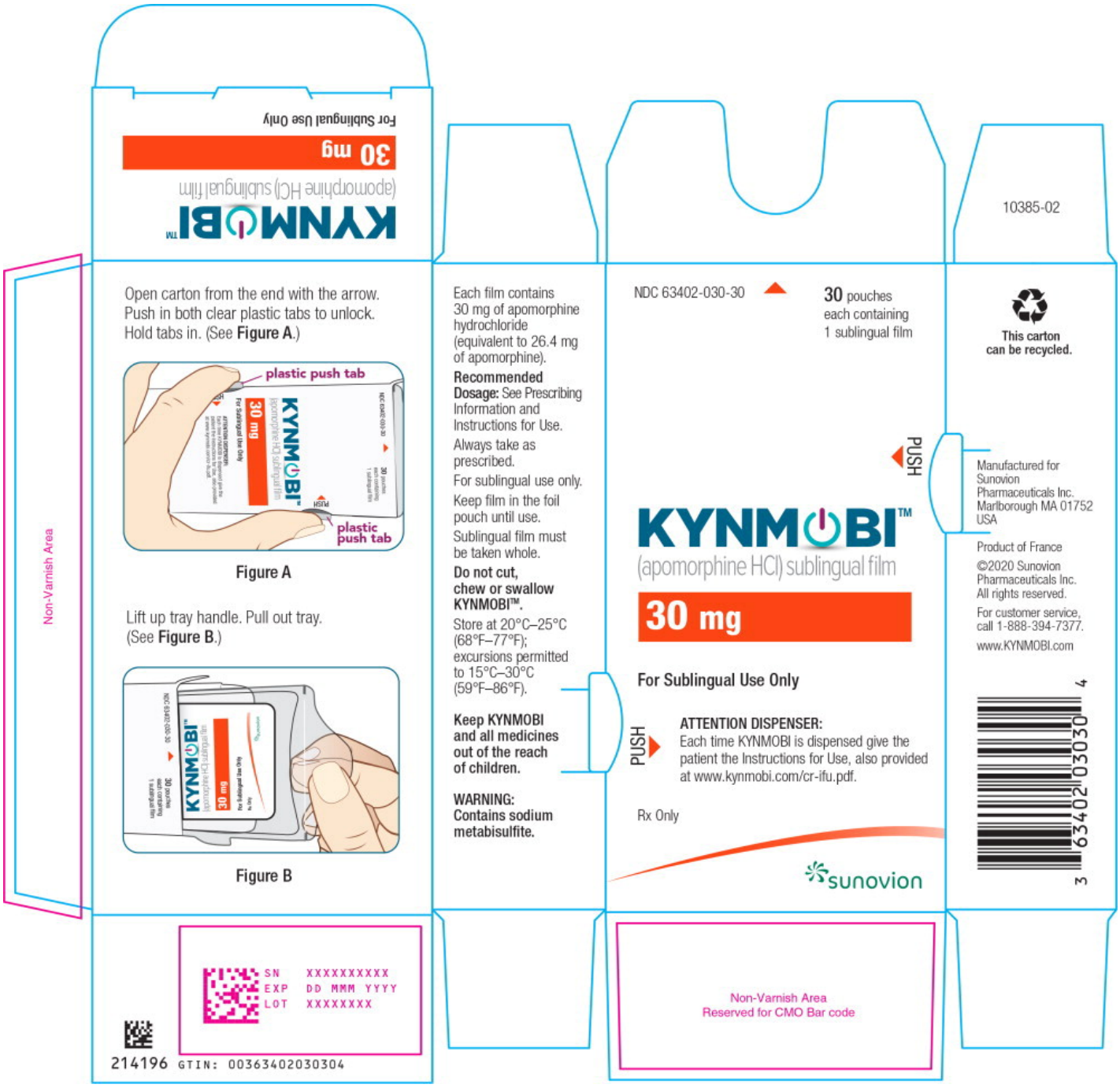
For Sublingual Use Only

ATTENTION DISPENSER:

Each time KYNMOBI is dispensed give the patient the Instructions for Use, also provided at www.kynmobi.com/cr-ifu.pdf

Rx only

SUNOVION



PRINCIPAL DISPLAY PANEL – TRADE OUTER TITRATION CARTON – 10 mg, 15 mg, 20 mg, 25 mg, 30 mg

NDC 63402-088-10 10 pouches each containing 1 sublingual film

KYNMOBI™

(apomorphine HCl) sublingual film

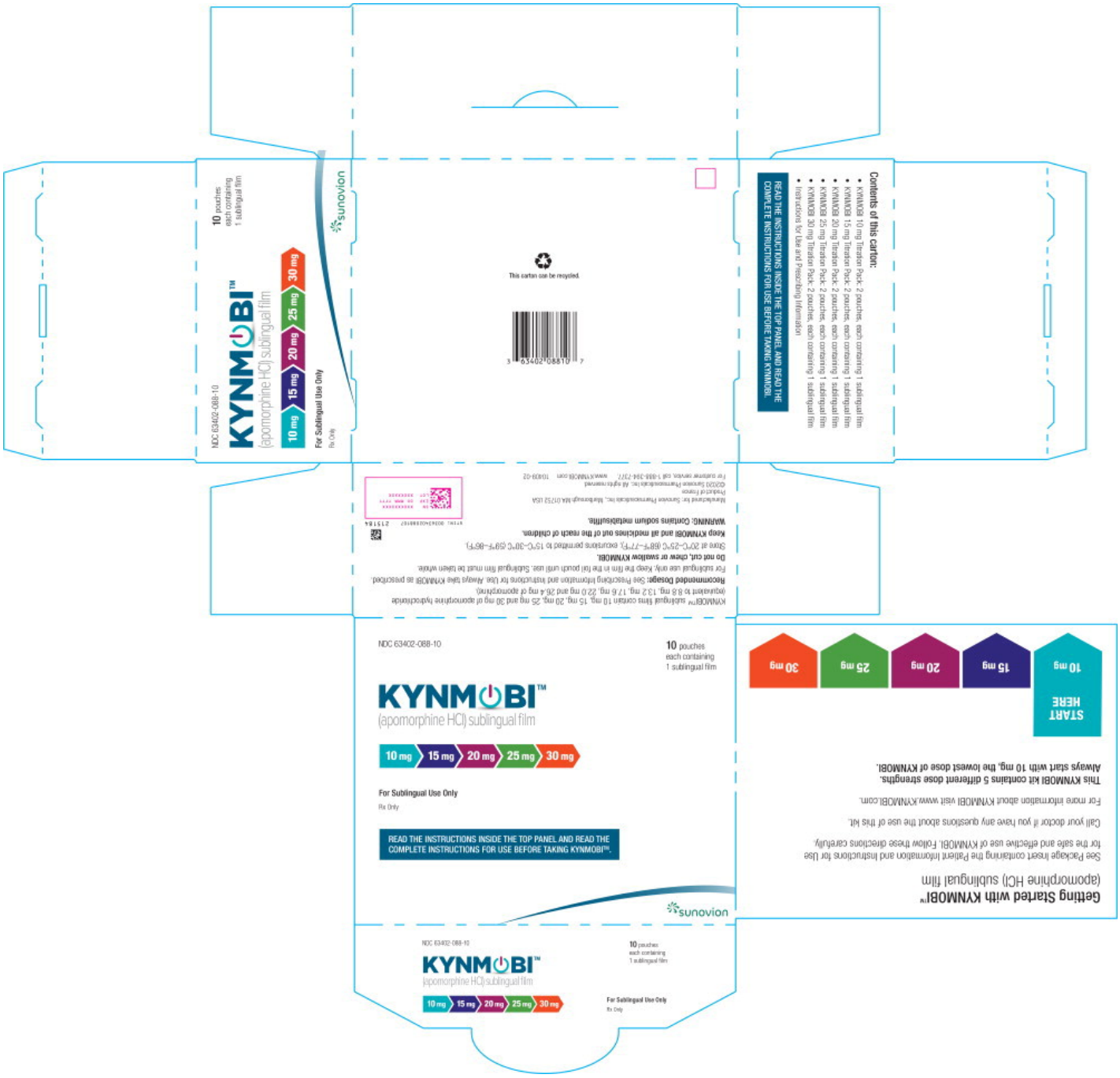
10 mg 15 mg 20 mg 25 mg 30 mg

For Sublingual Use Only

Rx only

READ THE INSTRUCTIONS INSIDE THE TOP PANEL AND READ THE COMPLETE INSTRUCTIONS FOR USE BEFORE TAKING KYNMOBI™

SUNOVION



PRINCIPAL DISPLAY PANEL – SAMPLE TITRATION CARTON – 10 mg, 15 mg, 20 mg, 25 mg, 30 mg

NDC 63402-188-10 10 pouches each containing 1 sublingual film

PROFESSIONAL SAMPLE – NOT FOR SALE OR REIMBURSEMENT

KYNMOBI™

(apomorphine HCl) sublingual film

10 mg 15 mg 20 mg 25 mg 30 mg

For Sublingual Use Only

Rx only

READ THE INSTRUCTIONS INSIDE THE TOP PANEL AND READ THE COMPLETE INSTRUCTIONS FOR USE BEFORE TAKING KYNMOBI™

CONTENTS OF THIS KIT:

KYNMOBI 10 mg: 2 pouches, each containing 1 sublingual film

KYNMOBI 15 mg: 2 pouches, each containing 1 sublingual film

KYNMOBI 20 mg: 2 pouches, each containing 1 sublingual film

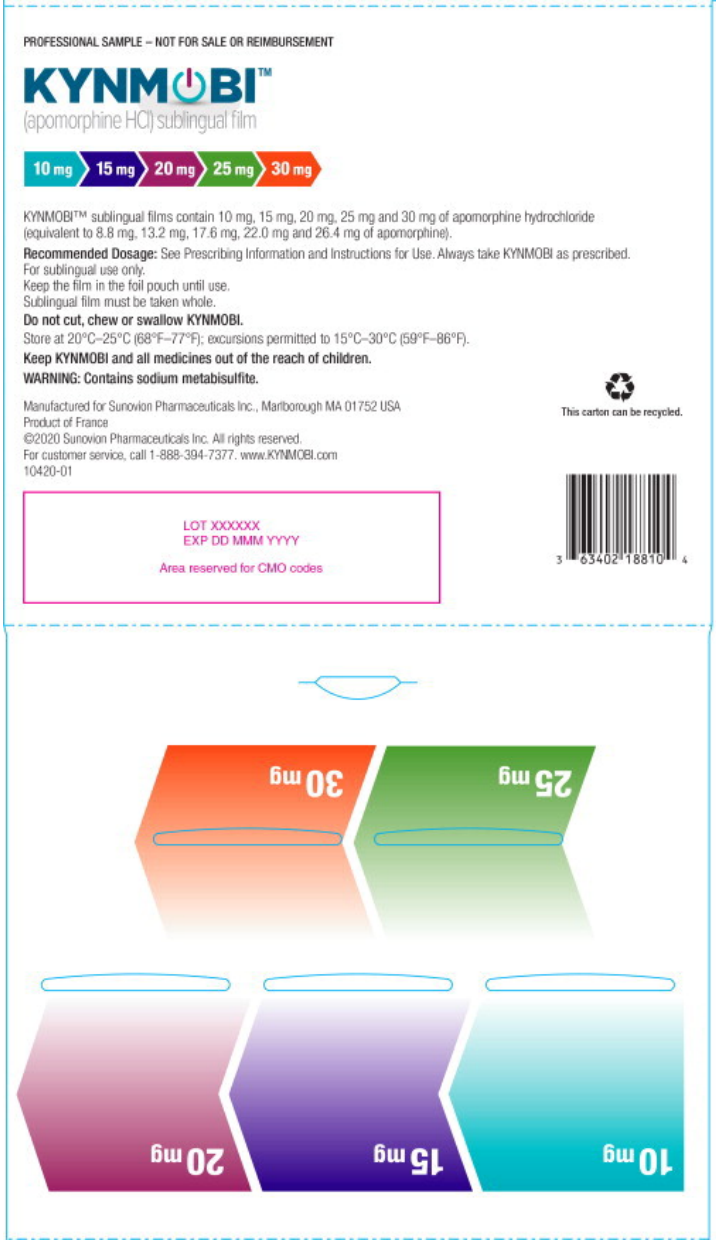
KYNMOBI 25 mg: 2 pouches, each containing 1 sublingual film

KYNMOBI 30 mg: 2 pouches, each containing 1 sublingual film

SUNOVION


sunovion
• instructions for Use and Prescribing Information
• KYNMOBI 10 mg: 2 pouches, each containing 1 sublingual film
• KYNMOBI 15 mg: 2 pouches, each containing 1 sublingual film
• KYNMOBI 20 mg: 2 pouches, each containing 1 sublingual film
• KYNMOBI 25 mg: 2 pouches, each containing 1 sublingual film
• KYNMOBI 30 mg: 2 pouches, each containing 1 sublingual film
CONTENTS OF THIS KIT:
READ THE INSTRUCTIONS INSIDE THE TOP PANEL AND READ THE COMPLETE INSTRUCTIONS FOR USE BEFORE TAKING KYNMOBI™.
For Sublingual Use Only
Rx Only
10 mg 15 mg 20 mg 25 mg 30 mg
KYNMOBI™
(apomorphine HCl) sublingual film
PROFESSIONAL SAMPLE – NOT FOR SALE OR REIMBURSEMENT
NDC 63402-188-10
10 pouches each containing 1 sublingual film


KYNMOBI™
(apomorphine HCl) sublingual film
Getting Started with KYNMOBI™
(apomorphine HCl) sublingual film
See Package Insert containing the Patient Information and Instructions for Use for the safe and effective use of KYNMOBI. Follow these directions carefully.
START HERE
Call your doctor if you have any questions about the use of this kit.
For more information about KYNMOBI visit www.KYNMOBI.com.
This KYNMOBI kit contains 5 different dose strengths. Always start with 10 mg, the lowest dose of KYNMOBI.


PROFESSIONAL SAMPLE – NOT FOR SALE OR REIMBURSEMENT
KYNMOBI™
(apomorphine HCl) sublingual film
10 mg 15 mg 20 mg 25 mg 30 mg
KYNMOBI™ sublingual films contain 10 mg, 15 mg, 20 mg, 25 mg and 30 mg of apomorphine hydrochloride (equivalent to 8.8 mg, 13.2 mg, 17.6 mg, 22.0 mg and 26.4 mg of apomorphine).
Recommended Dosage: See Prescribing Information and Instructions for Use. Always take KYNMOBI as prescribed.
For sublingual use only.
Keep the film in the foil pouch until use.
Sublingual film must be taken whole.
Do not cut, chew or swallow KYNMOBI.
Store at 20°C–25°C (68°F–77°F); excursions permitted to 15°C–30°C (59°F–86°F).
Keep KYNMOBI and all medicines out of the reach of children.
WARNING: Contains sodium metabisulfite.
Manufactured for Sunovion Pharmaceuticals Inc., Marlborough MA 01752 USA
Product of France
©2020 Sunovion Pharmaceuticals Inc. All rights reserved.
For customer service, call 1-888-394-7377. www.KYNMOBI.com
10420-01
This carton can be recycled.
LOT XXXXXX
EXP DD MMM YYYY
Area reserved for CMO codes
3 63402 18810 4

30 mg
25 mg
20 mg
15 mg
10 mg

KYNMOBI

apomorphine hydrochloride film, soluble

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63402-010
Route of Administration	SUBLINGUAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
apomorphine hydrochloride (UNII: F39049Y068) (apomorphine - UNII:N21FAR7B4S)	apomorphine hydrochloride	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
Pyridoxine hydrochloride (UNII: 68Y4CF58BV)	
sodium hydroxide (UNII: 55X04QC32I)	
sodium metabisulfite (UNII: 4VON5FNS3C)	
edetate disodium (UNII: 7FLD91C86K)	
menthol (UNII: L7T10EIP3A)	
glyceryl monostearate (UNII: 230OU9XXE4)	
Glycerin (UNII: PDC6A3C0OX)	
maltodextrin (UNII: 7CVR7L4A2D)	
Sucralose (UNII: 96K6UQ3ZD4)	
Hydroxyethyl cellulose (280 MPA.S AT 2%) (UNII: 12VCE9HR9E)	
hydroxyethyl cellulose (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
hydroxypropyl cellulose (45000 wamw) (UNII: 8VAB711C5E)	
FD&C Blue no. 1 (UNII: H3R47K3TBD)	
water (UNII: 059QF0KO0R)	
acetone (UNII: 1364PS73AF)	
alcohol (UNII: 3K9958V90M)	

Product Characteristics			
Color	blue (blue)	**Score**	no score
Shape	RECTANGLE (RECTANGLE)	**Size**	22mm
Flavor		**Imprint Code**	10
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63402-010-30	30 in 1 CARTON	05/21/2020	
1	NDC:63402-010-01	1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

NDA	NDA210875	05/21/2020	

KYNMOBI

apomorphine hydrochloride film, soluble

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63402-110
Route of Administration	SUBLINGUAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
apomorphine hydrochloride (UNII: F39049Y068) (apomorphine - UNII:N21FAR7B4S)	apomorphine hydrochloride	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
Pyridoxine hydrochloride (UNII: 68Y4CF58BV)	
sodium hydroxide (UNII: 55X04QC32I)	
sodium metabisulfite (UNII: 4VON5FNS3C)	
edetate disodium (UNII: 7FLD91C86K)	
menthol (UNII: L7T10EIP3A)	
glyceryl monostearate (UNII: 230OU9XXE4)	
Glycerin (UNII: PDC6A3C0OX)	
maltodextrin (UNII: 7CVR7L4A2D)	
Sucralose (UNII: 96K6UQ3ZD4)	
Hydroxyethyl cellulose (280 MPA.S AT 2%) (UNII: 12VCE9HR9E)	
hydroxyethyl cellulose (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
hydroxypropyl cellulose (45000 wamw) (UNII: 8VAB711C5E)	
FD&C Blue no. 1 (UNII: H3R47K3TBD)	
water (UNII: 059QF0KO0R)	
acetone (UNII: 1364PS73AF)	
alcohol (UNII: 3K9958V90M)	

Product Characteristics			
Color	blue (blue)	**Score**	no score
Shape	RECTANGLE (RECTANGLE)	**Size**	22mm
Flavor		**Imprint Code**	10
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63402-110-30	30 in 1 CARTON	05/21/2020	
1	NDC:63402-110-01	1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA210875	05/21/2020	

KYNMOBI

apomorphine hydrochloride film, soluble

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63402-015
Route of Administration	SUBLINGUAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
apomorphine hydrochloride (UNII: F39049Y068) (apomorphine - UNII:N21FAR7B4S)	apomorphine hydrochloride	15 mg

Inactive Ingredients

Ingredient Name	Strength
Pyridoxine hydrochloride (UNII: 68Y4CF58BV)	
sodium hydroxide (UNII: 55X04QC32I)	
sodium metabisulfite (UNII: 4VON5FNS3C)	
edetate disodium (UNII: 7FLD91C86K)	
menthol (UNII: L7T10EIP3A)	
glyceryl monostearate (UNII: 230OU9XXE4)	
Glycerin (UNII: PDC6A3C0OX)	
maltodextrin (UNII: 7CVR7L4A2D)	
Sucralose (UNII: 96K6UQ3ZD4)	
Hydroxyethyl cellulose (280 MPA.S AT 2%) (UNII: 12VCE9HR9E)	
hydroxyethyl cellulose (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
hydroxypropyl cellulose (45000 wamw) (UNII: 8VAB711C5E)	
FD&C Blue no. 1 (UNII: H3R47K3TBD)	
water (UNII: 059QF0KO0R)	
acetone (UNII: 1364PS73AF)	
alcohol (UNII: 3K9958V90M)	

Product Characteristics

Color	blue (blue)	**Score**	no score
Shape	RECTANGLE (RECTANGLE)	**Size**	22mm
Flavor		**Imprint Code**	15
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63402-015-30	30 in 1 CARTON	05/21/2020	
1	NDC:63402-015-01	1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA210875	05/21/2020	

KYNMOBI

apomorphine hydrochloride film, soluble

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63402-115
Route of Administration	SUBLINGUAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
apomorphine hydrochloride (UNII: F39049Y068) (apomorphine - UNII:N21FAR7B4S)	apomorphine hydrochloride	15 mg

Inactive Ingredients	
Ingredient Name	Strength
Pyridoxine hydrochloride (UNII: 68Y4CF58BV)	
sodium hydroxide (UNII: 55X04QC32I)	
sodium metabisulfite (UNII: 4VON5FNS3C)	
edetate disodium (UNII: 7FLD91C86K)	
menthol (UNII: L7T10EIP3A)	
glyceryl monostearate (UNII: 230OU9XXE4)	
Glycerin (UNII: PDC6A3C0OX)	
maltodextrin (UNII: 7CVR7L4A2D)	
Sucralose (UNII: 96K6UQ3ZD4)	
Hydroxyethyl cellulose (280 MPA.S AT 2%) (UNII: 12VCE9HR9E)	
hydroxyethyl cellulose (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
hydroxypropyl cellulose (45000 wamw) (UNII: 8VAB711C5E)	
FD&C Blue no. 1 (UNII: H3R47K3TBD)	
water (UNII: 059QF0KO0R)	
acetone (UNII: 1364PS73AF)	
alcohol (UNII: 3K9958V90M)	

Product Characteristics			
Color	blue (blue)	Score	no score
Shape	RECTANGLE (RECTANGLE)	Size	22mm

Flavor		**Imprint Code**	15
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63402-115-30	30 in 1 CARTON	05/21/2020	
1	NDC:63402-115-01	1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA210875	05/21/2020	

KYNMOBI

apomorphine hydrochloride film, soluble

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63402-020
Route of Administration	SUBLINGUAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
apomorphine hydrochloride (UNII: F39049Y068) (apomorphine - UNII:N21FAR7B4S)	apomorphine hydrochloride	20 mg

Inactive Ingredients	
Ingredient Name	**Strength**
Pyridoxine hydrochloride (UNII: 68Y4CF58BV)	
sodium hydroxide (UNII: 55X04QC32I)	
sodium metabisulfite (UNII: 4VON5FNS3C)	
edetate disodium (UNII: 7FLD91C86K)	
menthol (UNII: L7T10EIP3A)	
glyceryl monostearate (UNII: 230OU9XXE4)	
Glycerin (UNII: PDC6A3C0OX)	
maltodextrin (UNII: 7CVR7L4A2D)	
Sucralose (UNII: 96K6UQ3ZD4)	
Hydroxyethyl cellulose (280 MPA.S AT 2%) (UNII: 12VCE9HR9E)	
hydroxyethyl cellulose (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
hydroxypropyl cellulose (45000 wamw) (UNII: 8VAB711C5E)	
FD&C Blue no. 1 (UNII: H3R47K3TBD)	
water (UNII: 059QF0KO0R)	
acetone (UNII: 1364PS73AF)	
alcohol (UNII: 3K9958V90M)	

Product Characteristics			
Color	blue (blue)	**Score**	no score
Shape	RECTANGLE (RECTANGLE)	**Size**	22mm
Flavor		**Imprint Code**	20
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63402-020-30	30 in 1 CARTON	05/21/2020	
1	NDC:63402-020-01	1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA210875	05/21/2020	

KYNMOBI

apomorphine hydrochloride film, soluble

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63402-120
Route of Administration	SUBLINGUAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
apomorphine hydrochloride (UNII: F39049Y068) (apomorphine - UNII:N21FAR7B4S)	apomorphine hydrochloride	20 mg

Inactive Ingredients	
Ingredient Name	**Strength**
Pyridoxine hydrochloride (UNII: 68Y4CF58BV)	
sodium hydroxide (UNII: 55X04QC32I)	
sodium metabisulfite (UNII: 4VON5FNS3C)	
edetate disodium (UNII: 7FLD91C86K)	
menthol (UNII: L7T10EIP3A)	
glyceryl monostearate (UNII: 230OU9XXE4)	
Glycerin (UNII: PDC6A3C0OX)	
maltodextrin (UNII: 7CVR7L4A2D)	
Sucralose (UNII: 96K6UQ3ZD4)	
Hydroxyethyl cellulose (280 MPA.S AT 2%) (UNII: 12VCE9HR9E)	
hydroxyethyl cellulose (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
hydroxypropyl cellulose (45000 wamw) (UNII: 8VAB711C5E)	
FD&C Blue no. 1 (UNII: H3R47K3TBD)	

water (UNII: 059QF0KO0R)	
acetone (UNII: 1364PS73AF)	
alcohol (UNII: 3K9958V90M)	

Product Characteristics			
Color	blue (blue)	**Score**	no score
Shape	RECTANGLE (RECTANGLE)	**Size**	22mm
Flavor		**Imprint Code**	20
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63402-120-30	30 in 1 CARTON	05/21/2020	
1	NDC:63402-120-01	1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA210875	05/21/2020	

KYNMOBI

apomorphine hydrochloride film, soluble

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63402-025
Route of Administration	SUBLINGUAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
apomorphine hydrochloride (UNII: F39049Y068) (apomorphine - UNII:N21FAR7B4S)	apomorphine hydrochloride	25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
Pyridoxine hydrochloride (UNII: 68Y4CF58BV)	
sodium hydroxide (UNII: 55X04QC32I)	
sodium metabisulfite (UNII: 4VON5FNS3C)	
edetate disodium (UNII: 7FLD91C86K)	
menthol (UNII: L7T10EIP3A)	
glyceryl monostearate (UNII: 230OU9XXE4)	
Glycerin (UNII: PDC6A3C0OX)	
maltodextrin (UNII: 7CVR7L4A2D)	

Sucralose (UNII: 96K6UQ3ZD4)	
Hydroxyethyl cellulose (280 MPA.S AT 2%) (UNII: 12VCE9HR9E)	
hydroxyethyl cellulose (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
hydroxypropyl cellulose (45000 wamw) (UNII: 8VAB711C5E)	
FD&C Blue no. 1 (UNII: H3R47K3TBD)	
water (UNII: 059QF0KO0R)	
acetone (UNII: 1364PS73AF)	
alcohol (UNII: 3K9958V90M)	

Product Characteristics

Color	blue (blue)	**Score**	no score
Shape	RECTANGLE (RECTANGLE)	**Size**	22mm
Flavor		**Imprint Code**	25
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63402-025-30	30 in 1 CARTON	05/21/2020	
1	NDC:63402-025-01	1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA210875	05/21/2020	

KYNMOBI

apomorphine hydrochloride film, soluble

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63402-125
Route of Administration	SUBLINGUAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
apomorphine hydrochloride (UNII: F39049Y068) (apomorphine - UNII:N21FAR7B4S)	apomorphine hydrochloride	25 mg

Inactive Ingredients

Ingredient Name	Strength
Pyridoxine hydrochloride (UNII: 68Y4CF58BV)	
sodium hydroxide (UNII: 55X04QC32I)	
sodium metabisulfite (UNII: 4VON5FNS3C)	
edetate disodium (UNII: 7FLD91C86K)	

menthol (UNII: L7T10EIP3A)	
glyceryl monostearate (UNII: 230OU9XXE4)	
Glycerin (UNII: PDC6A3C0OX)	
maltodextrin (UNII: 7CVR7L4A2D)	
Sucralose (UNII: 96K6UQ3ZD4)	
Hydroxyethyl cellulose (280 MPA.S AT 2%) (UNII: 12VCE9HR9E)	
hydroxyethyl cellulose (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
hydroxypropyl cellulose (45000 wamw) (UNII: 8VAB711C5E)	
FD&C Blue no. 1 (UNII: H3R47K3TBD)	
water (UNII: 059QF0KO0R)	
acetone (UNII: 1364PS73AF)	
alcohol (UNII: 3K9958V90M)	

Product Characteristics

Color	blue (blue)	**Score**	no score
Shape	RECTANGLE (RECTANGLE)	**Size**	22mm
Flavor		**Imprint Code**	25
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63402-125-30	30 in 1 CARTON	05/21/2020	
1	NDC:63402-125-01	1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA210875	05/21/2020	

KYNMOBI

apomorphine hydrochloride film, soluble

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63402-030
Route of Administration	SUBLINGUAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
apomorphine hydrochloride (UNII: F39049Y068) (apomorphine - UNII:N21FAR7B4S)	apomorphine hydrochloride	30 mg

Inactive Ingredients

Ingredient Name	Strength
Pyridoxine hydrochloride (UNII: 68Y4CF58BV)	
sodium hydroxide (UNII: 55X04QC32I)	
sodium metabisulfite (UNII: 4VON5FNS3C)	
edetate disodium (UNII: 7FLD91C86K)	
menthol (UNII: L7T10EIP3A)	
glyceryl monostearate (UNII: 230OU9XXE4)	
Glycerin (UNII: PDC6A3C0OX)	
maltodextrin (UNII: 7CVR7L4A2D)	
Sucralose (UNII: 96K6UQ3ZD4)	
Hydroxyethyl cellulose (280 MPA.S AT 2%) (UNII: 12VCE9HR9E)	
hydroxyethyl cellulose (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
hydroxypropyl cellulose (45000 wamw) (UNII: 8VAB711C5E)	
FD&C Blue no. 1 (UNII: H3R47K3TBD)	
water (UNII: 059QF0KO0R)	
acetone (UNII: 1364PS73AF)	
alcohol (UNII: 3K9958V90M)	

Product Characteristics

Color	blue (blue)	**Score**	no score
Shape	RECTANGLE (RECTANGLE)	**Size**	26mm
Flavor		**Imprint Code**	30
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63402-030-30	30 in 1 CARTON	05/21/2020	
1	NDC:63402-030-01	1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA210875	05/21/2020	

KYNMOBI

apomorphine hydrochloride film, soluble

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63402-130
Route of Administration	SUBLINGUAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

apomorphine hydrochloride (UNII: F39049Y068) (apomorphine - UNII:N21FAR7B4S)	apomorphine hydrochloride	30 mg

Inactive Ingredients	
Ingredient Name	**Strength**
Pyridoxine hydrochloride (UNII: 68Y4CF58BV)	
sodium hydroxide (UNII: 55X04QC32I)	
sodium metabisulfite (UNII: 4VON5FNS3C)	
edetate disodium (UNII: 7FLD91C86K)	
menthol (UNII: L7T10EIP3A)	
glyceryl monostearate (UNII: 230OU9XXE4)	
Glycerin (UNII: PDC6A3C0OX)	
maltodextrin (UNII: 7CVR7L4A2D)	
Sucralose (UNII: 96K6UQ3ZD4)	
Hydroxyethyl cellulose (280 MPA.S AT 2%) (UNII: 12VCE9HR9E)	
hydroxyethyl cellulose (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
hydroxypropyl cellulose (45000 wamw) (UNII: 8VAB711C5E)	
FD&C Blue no. 1 (UNII: H3R47K3TBD)	
water (UNII: 059QF0KO0R)	
acetone (UNII: 1364PS73AF)	
alcohol (UNII: 3K9958V90M)	

Product Characteristics			
Color	blue (blue)	**Score**	no score
Shape	RECTANGLE (RECTANGLE)	**Size**	26mm
Flavor		**Imprint Code**	30
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63402-130-30	30 in 1 CARTON	05/21/2020	
1	NDC:63402-130-01	1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA210875	05/21/2020	

KYNMOBI

apomorphine hydrochloride kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63402-088

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63402-088-10	1 in 1 CARTON; Type 0: Not a Combination Product	05/21/2020	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	2 POUCH	2
Part 2	2 POUCH	2
Part 3	2 POUCH	2
Part 4	2 POUCH	2
Part 5	2 POUCH	2

Part 1 of 5

KYNMOBI

apomorphine hydrochloride film, soluble

Product Information	
Item Code (Source)	NDC:63402-010
Route of Administration	SUBLINGUAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
apomorphine hydrochloride (UNII: F39049Y068) (apomorphine - UNII:N21FAR7B4S)	apomorphine hydrochloride	10 mg

Inactive Ingredients	
Ingredient Name	Strength
Pyridoxine hydrochloride (UNII: 68Y4CF58BV)	
sodium hydroxide (UNII: 55X04QC32I)	
sodium metabisulfite (UNII: 4VON5FNS3C)	
edetate disodium (UNII: 7FLD91C86K)	
menthol (UNII: L7T10EIP3A)	
glyceryl monostearate (UNII: 230OU9XXE4)	
Glycerin (UNII: PDC6A3C0OX)	
maltodextrin (UNII: 7CVR7L4A2D)	
Sucralose (UNII: 96K6UQ3ZD4)	
Hydroxyethyl cellulose (280 MPA.S AT 2%) (UNII: 12VCE9HR9E)	
hydroxyethyl cellulose (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
hydroxypropyl cellulose (45000 wamw) (UNII: 8VAB711C5E)	
FD&C Blue no. 1 (UNII: H3R47K3TBD)	
water (UNII: 059QF0KO0R)	
acetone (UNII: 1364PS73AF)	

alcohol (UNII: 3K9958V90M)	

Product Characteristics			
Color	blue (blue)	**Score**	no score
Shape	RECTANGLE (RECTANGLE)	**Size**	22mm
Flavor		**Imprint Code**	10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63402-010-02	2 in 1 CARTON		
1	NDC:63402-010-01	1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA210875	05/21/2020	

Part 2 of 5

KYNMOBI

apomorphine hydrochloride film, soluble

Product Information	
Item Code (Source)	NDC:63402-015
Route of Administration	SUBLINGUAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
apomorphine hydrochloride (UNII: F39049Y068) (apomorphine - UNII:N21FAR7B4S)	apomorphine hydrochloride	15 mg

Inactive Ingredients

Ingredient Name	Strength
Pyridoxine hydrochloride (UNII: 68Y4CF58BV)	
sodium hydroxide (UNII: 55X04QC32I)	
sodium metabisulfite (UNII: 4VON5FNS3C)	
edetate disodium (UNII: 7FLD91C86K)	
menthol (UNII: L7T10EIP3A)	
glyceryl monostearate (UNII: 230OU9XXE4)	
Glycerin (UNII: PDC6A3C0OX)	
maltodextrin (UNII: 7CVR7L4A2D)	

Sucralose (UNII: 96K6UQ3ZD4)	
Hydroxyethyl cellulose (280 MPA.S AT 2%) (UNII: 12VCE9HR9E)	
hydroxyethyl cellulose (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
hydroxypropyl cellulose (45000 wamw) (UNII: 8VAB711C5E)	
FD&C Blue no. 1 (UNII: H3R47K3TBD)	
water (UNII: 059QF0KO0R)	
acetone (UNII: 1364PS73AF)	
alcohol (UNII: 3K9958V90M)	

Product Characteristics

Color	blue (blue)	**Score**	no score
Shape	RECTANGLE (RECTANGLE)	**Size**	22mm
Flavor		**Imprint Code**	15
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63402-015-02	2 in 1 CARTON		
1	NDC:63402-015-01	1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA210875	05/21/2020	

Part 3 of 5

KYNMOBI

apomorphine hydrochloride film, soluble

Product Information

Item Code (Source)	NDC:63402-020
Route of Administration	SUBLINGUAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
apomorphine hydrochloride (UNII: F39049Y068) (apomorphine - UNII:N21FAR7B4S)	apomorphine hydrochloride	20 mg

Inactive Ingredients

Ingredient Name	Strength

Pyridoxine hydrochloride (UNII: 68Y4CF58BV)	
sodium hydroxide (UNII: 55X04QC32I)	
sodium metabisulfite (UNII: 4VON5FNS3C)	
edetate disodium (UNII: 7FLD91C86K)	
menthol (UNII: L7T10EIP3A)	
glyceryl monostearate (UNII: 230OU9XXE4)	
Glycerin (UNII: PDC6A3C0OX)	
maltodextrin (UNII: 7CVR7L4A2D)	
Sucralose (UNII: 96K6UQ3ZD4)	
Hydroxyethyl cellulose (280 MPA.S AT 2%) (UNII: 12VCE9HR9E)	
hydroxyethyl cellulose (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
hydroxypropyl cellulose (45000 wamw) (UNII: 8VAB711C5E)	
FD&C Blue no. 1 (UNII: H3R47K3TBD)	
water (UNII: 059QF0KO0R)	
acetone (UNII: 1364PS73AF)	
alcohol (UNII: 3K9958V90M)	

Product Characteristics

Color	blue (blue)	**Score**	no score
Shape	RECTANGLE (RECTANGLE)	**Size**	22mm
Flavor		**Imprint Code**	20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63402-020-02	2 in 1 CARTON		
1	NDC:63402-020-01	1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA210875	05/21/2020	

Part 4 of 5

KYNMOBI

apomorphine hydrochloride film, soluble

Product Information

Item Code (Source)	NDC:63402-025
Route of Administration	SUBLINGUAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
apomorphine hydrochloride (UNII: F39049Y068) (apomorphine - UNII:N21FAR7B4S)	apomorphine hydrochloride	25 mg

Inactive Ingredients

Ingredient Name	Strength
Pyridoxine hydrochloride (UNII: 68Y4CF58BV)	
sodium hydroxide (UNII: 55X04QC32I)	
sodium metabisulfite (UNII: 4VON5FNS3C)	
edetate disodium (UNII: 7FLD91C86K)	
menthol (UNII: L7T10EIP3A)	
glyceryl monostearate (UNII: 230OU9XXE4)	
Glycerin (UNII: PDC6A3C0OX)	
maltodextrin (UNII: 7CVR7L4A2D)	
Sucralose (UNII: 96K6UQ3ZD4)	
Hydroxyethyl cellulose (280 MPA.S AT 2%) (UNII: 12VCE9HR9E)	
hydroxyethyl cellulose (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
hydroxypropyl cellulose (45000 wamw) (UNII: 8VAB711C5E)	
FD&C Blue no. 1 (UNII: H3R47K3TBD)	
water (UNII: 059QF0KO0R)	
acetone (UNII: 1364PS73AF)	
alcohol (UNII: 3K9958V90M)	

Product Characteristics

Color	blue (blue)	**Score**	no score
Shape	RECTANGLE (RECTANGLE)	**Size**	22mm
Flavor		**Imprint Code**	25
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63402-025-02	2 in 1 CARTON		
1	NDC:63402-025-01	1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA210875	05/21/2020	

Part 5 of 5

KYNMOBI

apomorphine hydrochloride film, soluble

Product Information

Item Code (Source)	NDC:63402-030
Route of Administration	SUBLINGUAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
apomorphine hydrochloride (UNII: F39049Y068) (apomorphine - UNII:N21FAR7B4S)	apomorphine hydrochloride	30 mg

Inactive Ingredients

Ingredient Name	Strength
Pyridoxine hydrochloride (UNII: 68Y4CF58BV)	
sodium hydroxide (UNII: 55X04QC32I)	
sodium metabisulfite (UNII: 4VON5FNS3C)	
edetate disodium (UNII: 7FLD91C86K)	
menthol (UNII: L7T10EIP3A)	
glyceryl monostearate (UNII: 230OU9XXE4)	
Glycerin (UNII: PDC6A3C0OX)	
maltodextrin (UNII: 7CVR7L4A2D)	
Sucralose (UNII: 96K6UQ3ZD4)	
Hydroxyethyl cellulose (280 MPA.S AT 2%) (UNII: 12VCE9HR9E)	
hydroxyethyl cellulose (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
hydroxypropyl cellulose (45000 wamw) (UNII: 8VAB711C5E)	
FD&C Blue no. 1 (UNII: H3R47K3TBD)	
water (UNII: 059QF0KO0R)	
acetone (UNII: 1364PS73AF)	
alcohol (UNII: 3K9958V90M)	

Product Characteristics

Color	blue (blue)	**Score**	no score
Shape	RECTANGLE (RECTANGLE)	**Size**	26mm
Flavor		**Imprint Code**	30
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63402-030-02	2 in 1 CARTON		
1	NDC:63402-030-01	1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA210875	05/21/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA210875	05/21/2020	

KYNMOBI

apomorphine hydrochloride kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63402-188

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63402-188-10	1 in 1 CARTON; Type 0: Not a Combination Product	05/21/2020	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 POUCH	2
Part 2	2 POUCH	2
Part 3	2 POUCH	2
Part 4	2 POUCH	2
Part 5	2 POUCH	2

Part 1 of 5

KYNMOBI

apomorphine hydrochloride film, soluble

Product Information

Item Code (Source)	NDC:63402-110
Route of Administration	SUBLINGUAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
apomorphine hydrochloride (UNII: F39049Y068) (apomorphine - UNII:N21FAR7B4S)	apomorphine hydrochloride	10 mg

Inactive Ingredients

Ingredient Name	Strength

Pyridoxine hydrochloride (UNII: 68Y4CF58BV)	
sodium hydroxide (UNII: 55X04QC32I)	
sodium metabisulfite (UNII: 4VON5FNS3C)	
edetate disodium (UNII: 7FLD91C86K)	
menthol (UNII: L7T10EIP3A)	
glyceryl monostearate (UNII: 230OU9XXE4)	
Glycerin (UNII: PDC6A3C0OX)	
maltodextrin (UNII: 7CVR7L4A2D)	
Sucralose (UNII: 96K6UQ3ZD4)	
Hydroxyethyl cellulose (280 MPA.S AT 2%) (UNII: 12VCE9HR9E)	
hydroxyethyl cellulose (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
hydroxypropyl cellulose (45000 wamw) (UNII: 8VAB711C5E)	
FD&C Blue no. 1 (UNII: H3R47K3TBD)	
water (UNII: 059QF0KO0R)	
acetone (UNII: 1364PS73AF)	
alcohol (UNII: 3K9958V90M)	

Product Characteristics

Color	blue (blue)	**Score**	no score
Shape	RECTANGLE (RECTANGLE)	**Size**	22mm
Flavor		**Imprint Code**	10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63402-110-01	1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA210875	05/21/2020	

Part 2 of 5

KYNMOBI

apomorphine hydrochloride film, soluble

Product Information

Item Code (Source)	NDC:63402-115
Route of Administration	SUBLINGUAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
apomorphine hydrochloride (UNII: F39049Y068) (apomorphine - UNII:N21FAR7B4S)	apomorphine hydrochloride	15 mg

Inactive Ingredients

Ingredient Name	Strength
Pyridoxine hydrochloride (UNII: 68Y4CF58BV)	
sodium hydroxide (UNII: 55X04QC32I)	
sodium metabisulfite (UNII: 4VON5FNS3C)	
edetate disodium (UNII: 7FLD91C86K)	
menthol (UNII: L7T10EIP3A)	
glyceryl monostearate (UNII: 230OU9XXE4)	
Glycerin (UNII: PDC6A3C0OX)	
maltodextrin (UNII: 7CVR7L4A2D)	
Sucralose (UNII: 96K6UQ3ZD4)	
Hydroxyethyl cellulose (280 MPA.S AT 2%) (UNII: 12VCE9HR9E)	
hydroxyethyl cellulose (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
hydroxypropyl cellulose (45000 wamw) (UNII: 8VAB711C5E)	
FD&C Blue no. 1 (UNII: H3R47K3TBD)	
water (UNII: 059QF0KO0R)	
acetone (UNII: 1364PS73AF)	
alcohol (UNII: 3K9958V90M)	

Product Characteristics

Color	blue (blue)	**Score**	no score
Shape	RECTANGLE (RECTANGLE)	**Size**	22mm
Flavor		**Imprint Code**	15
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63402-115-01	1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA210875	05/21/2020	

Part 3 of 5

KYNMOBI

apomorphine hydrochloride film, soluble

Product Information

Item Code (Source)	NDC:63402-120
Route of Administration	SUBLINGUAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
apomorphine hydrochloride (UNII: F39049Y068) (apomorphine - UNII:N21FAR7B4S)	apomorphine hydrochloride	20 mg

Inactive Ingredients

Ingredient Name	Strength
Pyridoxine hydrochloride (UNII: 68Y4CF58BV)	
sodium hydroxide (UNII: 55X04QC32I)	
sodium metabisulfite (UNII: 4VON5FNS3C)	
edetate disodium (UNII: 7FLD91C86K)	
menthol (UNII: L7T10EIP3A)	
glyceryl monostearate (UNII: 230OU9XXE4)	
Glycerin (UNII: PDC6A3C0OX)	
maltodextrin (UNII: 7CVR7L4A2D)	
Sucralose (UNII: 96K6UQ3ZD4)	
Hydroxyethyl cellulose (280 MPA.S AT 2%) (UNII: 12VCE9HR9E)	
hydroxyethyl cellulose (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
hydroxypropyl cellulose (45000 wamw) (UNII: 8VAB711C5E)	
FD&C Blue no. 1 (UNII: H3R47K3TBD)	
water (UNII: 059QF0KO0R)	
acetone (UNII: 1364PS73AF)	
alcohol (UNII: 3K9958V90M)	

Product Characteristics

Color	blue (blue)	**Score**	no score
Shape	RECTANGLE (RECTANGLE)	**Size**	22mm
Flavor		**Imprint Code**	20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63402-120-01	1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA210875	05/21/2020	

Part 4 of 5

KYNMOBI

apomorphine hydrochloride film, soluble

Product Information	
Item Code (Source)	NDC:63402-125
Route of Administration	SUBLINGUAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
apomorphine hydrochloride (UNII: F39049Y068) (apomorphine - UNII:N21FAR7B4S)	apomorphine hydrochloride	25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
Pyridoxine hydrochloride (UNII: 68Y4CF58BV)	
sodium hydroxide (UNII: 55X04QC32I)	
sodium metabisulfite (UNII: 4VON5FNS3C)	
edetate disodium (UNII: 7FLD91C86K)	
menthol (UNII: L7T10EIP3A)	
glyceryl monostearate (UNII: 230OU9XXE4)	
Glycerin (UNII: PDC6A3C0OX)	
maltodextrin (UNII: 7CVR7L4A2D)	
Sucralose (UNII: 96K6UQ3ZD4)	
Hydroxyethyl cellulose (280 MPA.S AT 2%) (UNII: 12VCE9HR9E)	
hydroxyethyl cellulose (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
hydroxypropyl cellulose (45000 wamw) (UNII: 8VAB711C5E)	
FD&C Blue no. 1 (UNII: H3R47K3TBD)	
water (UNII: 059QF0KO0R)	
acetone (UNII: 1364PS73AF)	
alcohol (UNII: 3K9958V90M)	

Product Characteristics			
Color	blue (blue)	**Score**	no score
Shape	RECTANGLE (RECTANGLE)	**Size**	22mm
Flavor		**Imprint Code**	25
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63402-125-01	1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA210875	05/21/2020	

Part 5 of 5

KYNMOBI

apomorphine hydrochloride film, soluble

Product Information

Item Code (Source)	NDC:63402-130
Route of Administration	SUBLINGUAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
apomorphine hydrochloride (UNII: F39049Y068) (apomorphine - UNII:N21FAR7B4S)	apomorphine hydrochloride	30 mg

Inactive Ingredients

Ingredient Name	Strength
Pyridoxine hydrochloride (UNII: 68Y4CF58BV)	
sodium hydroxide (UNII: 55X04QC32I)	
sodium metabisulfite (UNII: 4VON5FNS3C)	
edetate disodium (UNII: 7FLD91C86K)	
menthol (UNII: L7T10EIP3A)	
glyceryl monostearate (UNII: 230OU9XXE4)	
Glycerin (UNII: PDC6A3C0OX)	
maltodextrin (UNII: 7CVR7L4A2D)	
Sucralose (UNII: 96K6UQ3ZD4)	
Hydroxyethyl cellulose (280 MPA.S AT 2%) (UNII: 12VCE9HR9E)	
hydroxyethyl cellulose (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
hydroxypropyl cellulose (45000 wamw) (UNII: 8VAB711C5E)	
FD&C Blue no. 1 (UNII: H3R47K3TBD)	
water (UNII: 059QF0KO0R)	
acetone (UNII: 1364PS73AF)	
alcohol (UNII: 3K9958V90M)	

Product Characteristics

Color	blue (blue)	**Score**	no score
Shape	RECTANGLE (RECTANGLE)	**Size**	26mm
Flavor		**Imprint Code**	30
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63402-130-01	1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA210875	05/21/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA210875	05/21/2020	

Labeler - Sunovion Pharmaceuticals Inc. (131661746)

Revised: 6/2020 Sunovion Pharmaceuticals Inc.